“EVALUATION OF HOME BASED INSULIN THERAPY AND IT’S COMPLICATIONS”

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CERTIFICATE

This is to certify that the dissertation titled, **"Evaluation of home based insulin therapy and its complications"** submitted by **Dr.N.SOUNDARARAJAN**, to the Faculty of Pediatrics,**The Tamilnadu Dr.M.G.R Medical University**, Chennai, in partial fulfilment of the requirements for the award of **M.D. Degree (Pediatrics)** is a bonafide research work carried out by him under our direct supervision and guidance.

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CONTENTS

ABBREVIATION

SMBG	-	Self monitoring of blood glucose
DCCT	-	Diabetes Control and Complications Trial
HbA1c	-	Glycosylated hemoglobin
T1DM	-	Type1 diabetes mellitus
DKA	-	Diabetic ketoacidosis
WHO	-	World health organization
BMI	-	Body mass index
ICH&HC	-	Institute of child health and health centre
ADA	-	American Diabetic Association
UKPDS	-	United Kingdom Prospective Diabetic Study

ABSTRACT

BACKGROUND

Patient and Parents (Caregivers) Involvement forms the corner stone of management of chronic diseases such as diabetes.

OBJECTIVES

1) To assess the problems of Home based Insulin Therapy in Type I Diabetic Children less than 12 years. 2) To assess the impact of counseling on correction of error during home based insulin therapy.

METHODS

Home based Insulin therapy patients are counseled in the form of oral and video demonstrations, Interacting sessions and clarified the doubts in our hospital. 3 visits in three months interval. Total No of Patients 50.

In front of observer, patient load the Injection, during the procedure which of the following things are observed and recorded in proforma. 1) Order of loading 2) Accuracy of dose 3) Pre skin cleaning prior to injection 4) Skin pinch 5) Needle angle 6) Lime rotation 7) Site Rotation 8) Site related problem and blood drawn for check the level of Hba1c. Those patients pre and post counseling data entered and compared results are statistically analysed.

RESULTS

According to the study problems of home based insulin therapy are. 1) SMBG frequency 2) Accuracy of dose 3) Skin pinch 4) Needle angle 5) disposal of syringe 6) Local site problems 7) Site rotation and HbA1c.

Non Problematic area

Non Problematic areas are order of loading of insulin, pre skin cleaning, limb rotation.

Counseling and demonstration resulted in statistically significantly improvement seen. This emphasis the need for continued counseling and demonstration on all visits to the diabetic clinic.

CONCLUSION

The problems of home based insulin theraphy are identify namely. 1) SMBG frequently 2) Accuracy of the dose 3) Needle angle 4) Skin Pinch 5)Local Site problem 6) Site rotation and HBA1c control.

The problems are improved significantly with counseling and demonstration. Hence the need for continue diabetic education is obvious. This study emphasis the need for counseling by qualified personnel devoting plenty of time with demonstration improve quality and longevity of life and Juvenile diabetes.

Key words : type 1 diabetes mellitus, home based insulin theraphy, counseling, diabetic education.

INTRODUCTION

Diabetes mellitus[1] is a common chronic metabolic disease with hyperglycemia as the cardinal biochemical feature. Diabetes is classified according to the cause. First type is deficiency of insulin secretion due to beta cell damage in pancreas (Type 1 DM) and, second one is consequence of insulin resistance occurring in skeletal muscle, liver and adipose tissue along with various degree of beta cell impairment (Type 2). Most common endocrine metabolic disorder of adolescent and children is Type 1 DM with marked consequences of physical and mental development, and also Type 2 DM is increasingly diagnosed in youth. According to International Diabetic Federation[2] (IDF), 366 million people are living with DM resulting in prevalence rate of 8.3%. In this Type 1 DM accounts for 10-12 % of overall Diabetic patients. In our country, prevalence rate is 10.1 – 10.6 / 1,00,000 population, higher prevalence in urban than rural area. Among them men (11.56 / 100000) have higher prevalence than women (8.6 /100 000). Nowadays the prevalence of Diabetes is increasing globally as well as in India. Incidence of diabetes increase by 3% per year globally.

Diabetes is not a single entity. It is a heterogenous group of disorder in which distinct genetic pattern as well as other etiological factors and pathophysiological mechanisms interact leading to impairment of glucose tolerance.

Classification of diabetes mellitus according to etiological causes:

I.TYPE 1 Diabetes (β cell destruction leading to absolute insulin deficiency)

A. Immune mediated

B. Idiopathic

II.TYPE 2 DIABETES (predominantly insulin resistance with insulin deficiency, with minimal resistance)

III.OTHER SPECIFIC TYPES

A. Beta cell function defect (Genetic)

MODY 2

MODY 3

MODY 4 (Insulin promoter factor 1)

MODY 5 (HNF 1 BETA)

MODY 6 (NEURO D1)

MITOCHONDRIAL DNA

TYPE A INSULIN resistance

Lipoatropic diabetes

Leprechaunism

Beta cell action defect (Genetic)

RABSON Mendenhall syndrome

Others

B. Genetic defects in insulin action

C. Diseases of exocrine pancreas

D. Endocrinopathies

E. Drug /chemical induced

F. Infections

G. Uncommon forms

H. Genetic syndromes associated with diabetes

IV. GESTATIONAL DIABETES

Criteria to diagnose diabetes -

(According to American diabetic Association criteria[3])

1. FPG (fasting plasma glucose) > 126 mg /dl (7 mmol) (nil per oral > 8 hours).
2. 2 hrs PG > 200 mg/dl (11.1mmol/l) (during OGTT 75g GLUCOSE).
3. HBA1C > 6.5 % (perform lab using NGSP CERTIFIED METHOD AND standardized to DCCT assay).
4. RANDOM PG > 200 mg/dl (11.1mmol/l) in person with symptoms of hyperglycemia (if the hyperglycemia is equivocal repeat the test).

Diagnostic criteria for IGT (impaired glucose tolerance)

1. FBG 100-125 mg/ dl (5.6 -7.0 mmol/L)
2. 2 HOURS PLASMA GLUCOSE(oral glucose tolerance test) > 140 mg/dl but < 200 mg/dl (11.1 mmol/L)

Impaired glucose tolerance is a metabolic state between normal glucose homeostasis and diabetes. Many IGT individuals are euglycemic in their normal daily lives with normal or near normal HBAIC levels. Hyperglycemia manifests when only challenged with oral glucose used in the standard oral glucose tolerance test.

IGT is not a clinical entity but rather a risk factor for future Diabetes mellitus and cardio vascular diseases and it is often associated with insulin resistance, obesity particularly abdominal or visceral obesity, dyslipidemia of triglyceridemia or HDL /LDL type or both and hypertension. Insulin resistance is directly involved in pathogenesis of TYPE 2 diabetes.

Type 1 diabetes is characterized by low or absent level of endogenous insulin secretion.

It has 4 distinct stages

1. Pre Clinical beta cell auto immunity along with progressive defect in the insulin secretion.
2. Onset of the clinical diabetes mellitus
3. Transient remission ‘honey moon period’

4. Clinical diabetes associated with complications either acute or chronic and decreased life expectancy.

The predominant age of onset of childhood diabetes is 7 to 15 years, but may present at any age. The incidence of type 1 DM increased worldwide every year by 3 %. In type 1 DM both genetic & environmental factors involved in pathogenesis. Susceptibility to TYPE 1 Diabetes is genetically controlled by alleles of MHC (Major Histo compatibility complex) class 2 gene expressing HLA (Human Leukocyte Antigen) and also associated with autoantibodies to ICA (Islet cell of cytoplasm), Insulin and auto antibodies to GAD (Glutamic Acid Decarboxylase).

TYPE 1 DM also associated with some auto immune diseases like

1) Thyroiditis

2) Multiple sclerosis

3) Celiac disease and

4) Addison disease

In TYPE 1 DM, girls and boys are equally affected in younger age groups. The incidence of TYPE 1 is high in male population of Europe origin, and where as low incidence in non Europe origin and a female preponderance is noted after puberty F: M > 1.5 in Europe.

GENOTYPE

90 TO 95 % of young children in TYPE 1 DM[4] carry either one or both susceptibility haplotypes, 5% with HLA - conferred genetic susceptibility develop clinical DM. Risk of DM is 2 % when mother is diabetic, but when father is diabetic, risk increases to 7%, In monozygotic twins risk is 30 – 65 % but in dizygotic twins risk is only 7- 10 %. Most of the Type 1 DM patients don't have single gene defect, classical single gene defect is extremely rare. Risk of developing DM is modified by the influence of several risk loci. Great contribution to the risk is from HLA on chromosome 6, other region is promoter region 5 of insulin gene on chromosome 11 and also several other loci involved like PTPN2, PTPN22, Interleukin -2 receptor CD25, CTLA 4, ERBB 3e, in which PTP N 22 has less useful in predicting genetic risk of TYPE 1 DM. Other risk factors identified in epidemiological studies, operate in early life and trigger the immune mediated process in genetically risky patients. Timing of introduction of cereals / gluten and other foods to infant diet alter risk of autoimmunity & T1 DM. Increasing the use of supplementation of Vit D reduces risk of T1DM. High maternal consumption of Vit D during pregnancy reduce the risk of islet autoimmunity, also protective effect observed in serum alpatocopherol in TYPE 1 DM

PATHOGENESIS OF DIABETES MELLITUS

TYPE 1DM in a susceptible host develops autoimmunity against their own beta cells, but what triggers the auto immune response is not known. In some of them, auto immune response results in progressive destruction of beta cells until critical level of mass lost and deficiency of insulin develops. Deficiency of insulin leads to onset of clinical signs and symptoms of diabetes. In some of patients some amount of viable beta cells are present and that produces enough insulin and leads to partial remission of the disease (known as honey moon period).

Over a period of time nearly all beta cells are destroyed and the patient depends on exogenous insulin. Then over a period of time some of the patients develop secondary complication of diabetes mellitus that is proportionate to how well they control the disease.

COURSE OF THE DISEASE

The following stages are seen-

1. Auto immunity initiation
2. Pre clinical auto immunity and progressive loss of beta cells
3. Clinical onset of diabetes with signs and symptoms
4. Transient remission of diabetes
5. Clinically established disease
6. Development of complication of disease

CLINICAL ONSET OF DIABETES

90 % of beta cell mass is destroyed at the time of clinical disease. Beta cell destruction is more rapid and complete in younger children, while older age group and adults have high percentage of beta cell preserved (10 to 20%) compared to younger age groups. The surviving mass of beta cells present at the time of diagnosis is important in newly diagnosed case because it increase the possibility of secondary prevention in TYPE 1DM.

PATHOPHYSIOLOGY OF TYPE 1 DIABETES

Insulin plays a major role in storage and retrieval of cellular fuel. Insulin secretion in response to feeding is modulated by interplay of neuronal, hormonal and substrate level mechanisms. Insulin level both in anabolic state and in catabolic state will affect the liver muscle and adipose tissue. Type1DM is a progressive catabolic low insulin state, feeding does not reverse this state. In reverse it exaggerates the state. In this state (low insulin catabolic) glucose utilization by liver and muscle will reduces and results in postprandial hyperglycemia. Even in lower level of insulin, liver produces excess of glucose by glycogenolysis and neo glucogenesis, will result in fasting hyperglycemia. Hyperglycemia will manifest as osmotic diuresis when renal threshold exceed 180 mg /dl which results in loss of calories and electrolytes as well as persistent

dehydration. This leads to stress & produces stress hormones. These hormones causes further metabolic decompensation, further reduce secretion of insulin. The combination insulin deficiency and increased counter regulatory hormones are reasons for lipolysis and impaired lipid synthesis and lead to increased level of cholesterol, total lipids, triglycerides and free fatty acids. Hormonal interplay of low insulin and high level of glucagon shunts free fatty acid to ketone body formation. If the formation exceeds the peripheral utilization, that is excreted in urine.

Accumulation of ketone bodies

↓

Metabolic acidosis

↓

Compensatory rapid breathing

↓

Dehydration, hyperosmolarity

↓

Diminished Cerebral oxygen utilization

↓

Coma

CLINICAL FEATURES OF TYPE 1 DM

Diabetics develop symptoms which steadily increases and reflects decreasing beta cell mass. When level of glucose is sufficiently high above the renal threshold, intermittent polyuria or nocturnal symptoms

starts.When chronic hyperglycemia leads to persistent diuresis, polydipsia become more prominent. If the affected patient is female, she may develop monilial vaginitis due to chronic glycosuria. More calories are lost in urine, that trigger hyperphagia. This hyperphagia does not keep in pace, with intake loss of fat from the body occurs.

In extreme low insulin levels, ketone bodies accumulate and child deteriorates quickly. These keto acids produce nausea, abdominal discomfort and pain and lead to dehydration. But persistence of polyuria & ketoacidosis exacerbate the symptoms such as increased respiration which is deep and rapid with fruity odor, reduced neuro cognitive function & possibly coma. 1/3 of patients present with DKA when they are not yet diagnosed.

DIANOSIS OF TYPE 1 DIABETES

Most of symptoms are non specific, important symptoms are inappropriate polyuria with dehydration, poor weight gain, non fasting plasma glucose level > 200 mg/dl, along with symptom of diabetes is diagnostic, associated with or without ketonuria. Once hyperglycemia is confirmed, it is prudent to check ketonuria present or not with electrolyte imbalance. Estimate the baseline HBA1C level to identify the duration of the disease also to compare the effectiveness of the therapy. In non obese children testing the auto immunity for beta cells is

not indicated, other auto immunity associated with diabetes to be investigated.

1. Thyroiditis (anti thyroid peroxidase, anti-thyroglobulin anti bodies)
2. Celiac diseases (tissue transglutaminase IgA, and total IgA)

CRITERIA FOR SCREENIG OF DIABETES

Risk of developing type 1 DM screened by presence of GADA (Glutamic acid decaboxylase auto antibodies) , PIA (Pancreatic Islet auto antibodies , IA-2 (Insulinoma associated Auto Antibodies). Screening is recommended for family history of type 1 DM in siblings, and considers the age of onset, sex, genetic markers and C- Peptide assay.

ADA current recommendation is considering the referral of relatives of Type 1 DM for antibodies testing and assessment of the risk .

RECOMMENTATIONS

TYPE 1DM patient's first degree relatives are screened for pancreatic beta cell anti bodies and OGTT also recommended. Also annual measurement of thyroid stimulating hormone and screening the diabetic children for celiac disease and other associated auto immune disorders. It is also important to monitor the growth and puberty.

MANAGEMENT OF TYPE 1 DIABETES

Management of type 1 DM needs team approach, patients and family members must be educated in self management of diabetes including prevention and first aid management related to emergencies in this disease, lifelong insulin therapy and nutrition therapy, planned physical activity and self monitoring of blood glucose. Psychological problems must be anticipated and addressed in time. Therefore the goal of the treatment is to keep the child symptom free, ensure the normal growth and development with HBA1C level as close to the normal range as possible. The lower Glycosylated Hemoglobin level, lower the risk of development of long term micro /macro vascular complications.

Regular screening for long term complications and co morbid conditions is warranted. Replacement of missing hormone insulin is not the only aspect of management of DM, also Equal importance given to four thematic pillars and they are

1) Insulin therapy
2) Medical nutrition therapy (meal planning)
3) Planned physical activity
4) Self monitoring of blood glucose and blood and urinary ketone bodies

INSULIN THERAPY

Fundamentals of Insulin Management[5]

ADA (American Diabetes Association) recommended the terminology

1. Basal insulin
2. Prandial insulin
3. Nutritional insulin
4. Correction insulin used in type I diabetic management therapy

BASAL INSULIN

Needed consistently to prevent the diabetic ketoacidosis

PRANDIAL INSULIN

Need to prevent the post prandial raise of blood glucose caused by peripheral glucose disposal at the level of muscle.

NUTRITIONAL INSULIN

Used for instead of prandial insulin when calories provided by total parental nutrition or NG feeding.

CORRECTION INSULIN

This is additional insulin given for correcting the hyperglycemia.

In healthy non stress individuals one unit of normal insulin will reduce the glucose approximately 50mg/dl (1:50) and one unit of insulin will cover 15g of carbohydrate (1:15). These ratios vary with individual, age, sex, pubertal status, weight and general activity.

TYPES OF INSULIN[6]

Meal time insulin

Rapid acting insulin analogues

1) lispro
2) Aspart

1. LISPRO

In comparison to regular insulin lispro peaks rapidly, lower the post prandial glucose level and prevent hyperglycemia. It is administered 30 minutes before food.

2. ASPART

In comparison to lispro, it significantly reduces the HBA1C and but does not cause frequent hypoglycemia

SHORT ACTING HUMAN INSULIN - REGULAR

It is injected subcutaneously and has slower rate of absorption. It has onset of action 15-60 min after injection, peak 2-4 hrs and duration of action 5-8hrs. It is given half an hour before meals.

BASAL INSULIN

Intermediate acting human insulin, has more prolonged action so they are not ideal for controlling postprandial glucose level.

LONG ACTING INSULIN

This is otherwise called as Ultra lente insulin. Most patients require only one injection of basal insulin per day at bed time.

MEDICAL NUTRITION THERAPY[7]

Medical nutrition therapy provide information, motivation and problem solving technique for meal planning and family nutrition for children with diabetes. It is a integral component of any any successful diabetic self management.

General nutritional goals for a diabetic child includes;

1. To reach and maintain the optimal blood glucose level.
2. To achieve a optimal lipid and lipoprotein level.
3. To maintain an optimal blood pressure.

4. To prevent and treat the complications of diabetes.
5. To provide adequate calories for the maintenance of acceptable weight, normal growth and developmental rates of the diabetic children.

Food and feeding issues are very important part of physical and psychological growth of diabetic children.

Dietary education must be done differently to each children and depends on developmental state and family dynamics. The diabetic children should have the balance between food, insulin therapy and everyday activities as there is already a need for physical maturity. Frequent assessment of diet and careful monitoring of growth are important aspects of medical nutrition therapy. There can be a wide variation of caloric need in children with diabetes. The caloric need changes according to work in which child involves, such as school activities, works at home, weekend recreations, vocation and sports activities continued nutritional follow up and education are required for every 6 months to 1 year.

Nutritional recommendations for protein, carbohydrate and fat content to achieve optimum metabolic control in children with diabetes includes

1. Amount of fat should not exceed 30% of total calories, in which less than 10% from saturated fat, less than 10% from poly unsaturated fats and 10-15% from mono unsaturated fats.
2. Dietary cholesterol should be limited to less than 300 mg/day.
3. Carbohydrates and mono saturated fat should contribute to 60-70% of meal plan.
4. 2.2 gram/kg/day of protein should be provided for infants with diabetes.
5. 0.9 gram/ kg /day of protein should be provided adolescents with diabetes.

In Indian journal of endocrinology and metabolism, the first indian recommendation for best injection practice by Sanjay kalra et al[8] and First Indian Insulin. Injection technique guidelines by FIT (Forum for Injection Technique) provides important information which is useful for self care of diabetic patients to achieve optimal glycemic control.

NEED FOR GUIDELINES:

Therapeutic success of insulin is highly operator dependent. Factors influencing the techniques are following.

- ❖ Modifiable Factors
- ❖ Non Modifiable Factors

Modifiable factors	Non modifiable factors
1) Method of administration	1) Visual impairment
2) Dosing	2) Hearing impairment
3) Compliance	3) Basic education
4) Selection sites	4) Learning skill
5) Misconception about therapy	
6) Clinician knowledge and time	

The Indian health care practices are mostly hospital or physician based rather than guide line based like other developing countries. So the need for pre injection evaluation, psychotherapy and counseling.

In diabetes mellitus it is important to include the children and parents as important partners in this disease care. Explanation of role of insulin in management and need for regular therapy, using simple comprehensible words.

STORAGE OF INSULIN

Injection is to be stored in room temperature in a dark place (15-25^{0}C) and discarded after 30 days of initial use, Extremes of temperature should be avoided.

COMPATIABILITY OF SYRINGE AND VIAL

It is important to inject correct insulin in correct syringe.

In our country both 40u/ml and 100u/ml vials are available, use 40u vial for 40u syringe and 100u vial for 100u syringe.

BEST SITES FOR INJECTION

In diabetic patients insulin is administered subcutaneously in stress free condition. Intravenous infusion and intramuscular sites are used for stressful condition like DKA.

ANTERIOR ABDOMEN WALL

It is most frequent injection site administered below the straight line 2.5 cm above umbilicus and vertical line 5cm away from umbilicus.

UPPER ARM

Insulin is administered subcutaneously in Posterior middle 3^{rd} of arm between shoulder and elbow

ANTERIOR THIGH

Insulin is administered subcutaneously in anterior and outer mid third aspect of thigh. The order of rate of absorption site is abdomen>

arm > thigh. There is less presence of fat and no major nerves in this region.

SKIN FOLD FOR INJECTION

Thumb and index finger used to make a fold (along with middle finger) and lifted skin fold should not be squeezed tightly. The sequence of lifted skin fold is

- Make lifted skin fold and insert the needle into skin at 90^0 angle.
- Administer the insulin
- Withdraw needle from skin fold
- Release the fold

BARRIER TO INSULIN THERAPY

The success of home based insulin therapy is based on identifying and correcting the barrier.

BARRIERS IN PATIENT SIDE

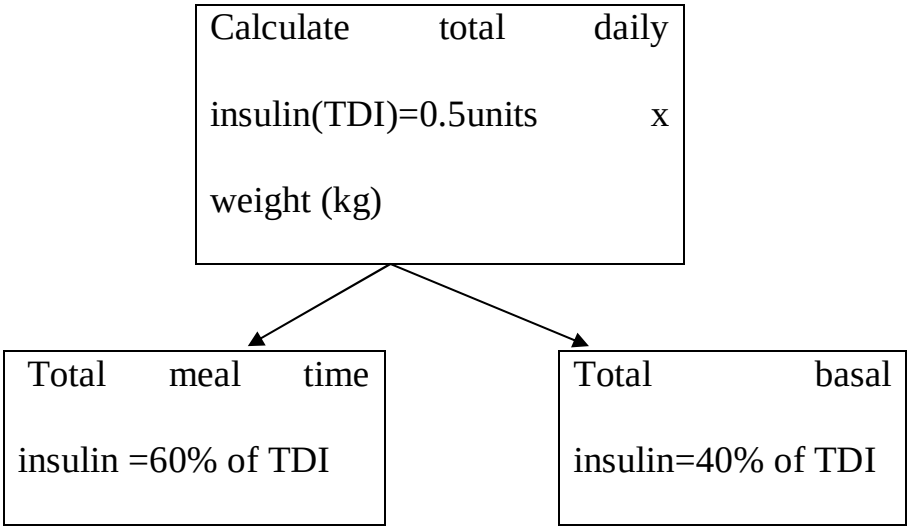
This is corrected by asking open ended and non judge mental questions and help the patient to disclose their concern and implement the effective way of management.

BARRIERS IN PHYSICIAN

Physician related barrier is delay in initiating the insulin in time and concern about delay in identifying the adherence, hypoglycemia and weight gain and other minor factors. Lack of support of paramedical workers like diabetic department trained staff also acts as a barrier.

GOALS OF INSULIN THERAPY

1. Free from symptoms of hyperglycemia
2. To prevent diabetic ketoacidosis
3. To assess severe catabolic state and regain lean body mass, reduce the frequency of injection, to prevent and delay the micro/macro vascular complications.



If a patient is newly diagnosed type 1 DM usual daily insulin requirement is 0.5 to 0.7 units /kg/day. Half of the dose should be given as basal insulin and reminder as prandial insulin.

MEDICAL NUTRITION THERAPY

As recommended by American diabetes Association goals in type 1 diabetes.

i. Individualized meal plan based on usual food intake and life style.
ii. Consistency of carbohydrate intake to allow synchronization of meal times with fixed time of insulin regimens.
iii. Determination of insulin dose and post prandial glucose level monitoring and adjust the insulin dose.
iv. Prevention of weight gain.
v. Adjustment of rapid or short acting insulin according to food intake.

EDUCATION IN TREATMENT OF DIABETES

Improve the well being and quality of life, also improve self care practices. But psychological factors should also be given importance.

i. Emotional based coping styles.
ii. TYIDM related distress.

iii. Lack of readiness to change.

iv. Positive emotional outlook about diabetes.

METABOLIC CONTROL

DCCT (Diabetic control and complication trial) and UKPDS (United kingdom prospective diabetes study) were the two studies, conducted to evaluate the importance of good glycemic control. Both these studies had established the importance of good glycemic control in reducing the short and long term complications.

Multidisciplinary team includes health care Practitioner / Educator & Nutritionist. The role of other team members like psychologist, pharmacist, ophthalmologist are now being recognized well.

PREVENTION AND EARLY DETECTION OF COMPLICATIONS

Diabetic education plays the major role in the prevention and early detection of complications of type 1 DM. Studies have confirmed that patients who do not receive the education were at increase risk of complications. Further self management and insulin skills depends on diabetic education which also has protective effect on risk of complications.

Diabetic education programs are evolving as a part and multifaceted diabetic management efforts provided by skilled health care

team that help the patients to reach high level of adherence and metabolic control. Diabetic patient education services should be accessible to every diabetic patient.

COMPLICATIONS OF TYPE I DM

Complications can be classified as acute, intermediate and chronic complications.

ACUTE COMPLICATIONS

1. Diabetic ketoacidosis
2. Hypoglycemia

INTERMEDIATE COMPLICATIONS

1. Lipoatrophy.
2. Limited joint mobility
3. Growth failure
4. Delay in sexual maturation
5. Hypoglycemic unawareness

CHRONIC COMPLICATIONS

1. Retinopathy
2. Peripheral neuropathy
3. Nephropathy
4. Dyslipidemia
5. Celiac disease

DIABETIC KETO ACIDOSOSIS

This is the most severe complication of Type 1 diabetes mellitus and characterized by hyperglycemic dehydration and associated ketotic acidemia. It results from a state of insulin deficiency and most common cause of diabetes related deaths in Type 1 DM. Diabetic ketoacidosis is because of a decline in circulating insulin levels and a related increase in counter regulatory hormones like glucagon, catecholamines, cortisol and growth hormone and usual precipitating factors includes unusual physical stress, infection, or in known diabetic patients omission of insulin injections.

Typically blood sugar level is above 250 mg /dl, ketones positive at >1:2 dilution, serum pH is less than 7.3 and serum bicarbonate is less than 15 m.eq/ l. The biochemical criteria for the diagnosis of DKA include.

1. Hyperglycemia : Blood glucose more than 200 mg/ dl.
2. Venous pH less than 7.3 or bicarbonate less than 15 mmol/litre.
3. Glycosuria, ketonuria and ketonemia.

CATEGORIZATION OF SEVERITY

Categorization of severity depends on the acidosis observed in DKA.

1. **MILD VARIETY**

   Venous pH is between 7.20 to 7.30 and bicarbonate level is in between 10 to 15 m.mol/litre.

2. **MODERATE VARIETY**

   Venous Ph is between 7.10 to 7.30 and bicarbonate level is in between 5 to 10 m.mol/litre.

3. **SEVERE VARIETY**

   Venous Ph is less than 7.10 and bicarbonate level is less than 5 m.mol/litre.

CLINICAL PRESENTATION

DKA can present as a primary presentation of type 1 DM and around 15 to 70% of all newly diagnosed patients present with DKA. The overall rate of DKA in type 1 DM patient remains as 25%. The

prevalence of DKA decreases from 36% in aged less than 5 years to 16% in aged more than 14 years old.

DKA is most frequently observed in children who were non-compliant to insulin therapy. Patients using insulin pumps are more prone to DKA as malfunction of pump may lead to interruption in insulin flow. Sometimes it presents as a case of acute abdomen. The most common symptoms are abdominal pain, nausea, vomiting, polyuria, dyspnoea and polydipsia.

The physical examination may reveal

- Tachycardia
- Dry mucous membranes
- Reduced skin turgor
- Hypotension
- Tachypnoea
- Kussmaul respiration
- Respiratory distress
- Abdominal tenderness
- Lethargy
- Cerebral edema
- Coma

In all patients a precipitating factor should be sought. Infection is the most common precipitating factor. The metabolic derangements may take long time to develop, but the symptoms and signs develop within 24 hours.

COMPLICATIONS OF DKA

1. Cerebral edema (most dreaded and a fatal complication)
2. Hypokalemia
3. Hypoglycemia
4. Septic shock
5. Cerebral hemorrhage or thrombosis. (DKA is prothrombotic state)
6. Pancreatitis

MONITORING AND INVESTIGATIONS

- Admission is intensive care unit is necessary in children with moderate and severe categories of DKA.
- Hourly monitoring of heart rate, respiratory rate, BP, SpO_2.
- Hourly input and output chart.
- Hourly pupils and neurological examination is necessary for warning signs and symptoms of cerebral edema.This includes head ache, increasing BP, bradycardia, vomiting, restlessness, irritability, drowsiness, incontinence, cranial nerve palsies and unequal pupils.

- Hourly blood glucose level. If capillary blood glucose is used cross checking with venous glucose value is necessary as CBG is not accurate in poor peripheral circulation.
- 2 to 4 hourly blood gases and electrolytes.
- 8 to 12 hourly urea and hematocrit.

MANAGEMENT

1. Correction of dehydration

   Though dehydration is seen in all patients, shock is rare because of the hyperosmolar state which results in fluid shift to maintain the intravascular volume. Counter regulatory hormones like cortisol also helps to maintain the BP.

   If shock is present resuscitation with boluses of 10 ml/kg of 0.9% saline over 30-60 minutes. Initial boluses are not necessary for dehydration without shock. The degree of dehydration is generally 5-8%. Rehydration should be achieved with NS that is infused over 48 hours.

2. Correction of acidosis and bicarbonate therapy

   DKA patients have a wide anion gap metabolic acidosis because of presence of excess ketones and lactate. Fluid replacement with insulin therapy will effectively correct acidosis. Majority of

patients do not need bicarbonate therapy. However indications for bicarbonate therapy are infrequent and includes

1. Severe acidosis
2. Refractory shock
3. Life threatening hyperkalemia

The required dose of bicarbonate (in m.mol) is calculated by following formula $0.3 \times weight\ in\ kg \times base\ deficit$

Half of the calculated dose should be infused over 4 hours then again patients ABG should be checked. Stop bicarbonate therapy when Ph is more than 7.

POTTASIUM REPLACEMENT

This should be started before the commencement of insulin infusion.

INSULIN INFUSION

Initial bolus of insulin is not required and should be given as a in fusion through a dedicated iv line. IV line needs to be primed with insulin containing solution, as insulin may bind with this tubings. Infusion should be started at the rate of 0.05 to0.1 units/kg/hr.

Aim for the fall in blood glucose level is 100 mg/dl/hr. Titrations should be done in infusion rate to keep the blood glucose level

between 100-200 mg/dl.It can be stopped when the child is alert and metabolically stable.

SODIUM REPLACEMENT

Hyponatremia is factitious or translocational hyponatremia. A corrected sodium level should be obtained.If corrected sodium is above 150 meq/litre it means a hypernatremic and independent glucose hyperosmolol state exists.

CEREBRAL EDEMA

Risk factors include

1. Severe hypocapnia at presentation.
2. Increased serum urea nitrogen at presentation.
3. Failure of measured serum sodium concentrations to rise during therapy.
4. Severe acidosis at presentation.

Should the evidence of brain herniation to develop the time for effective therapy is short short. If doubt arises patient should be intubated and osmolar therapy should be started. Mannitol 1-1.5 g/kg iv infusion or 3% hyper tonic may be used to increase the serum osmolality by 5-10 mOsm/kg and to decrease cerebral edema.

Mortality rate in paediatric population varies between 0.15 to 0.3%.Cerebral edema is related with 60-90% of deaths related to DKA.

LIMITING FACTORS OF GLYCEMIC CONTROL

Glycemic control reduces the microvascular complications like nephropathy, neuropathy, retinopathy also may reduce macro vascular complications.

Iatrogenic hypoglycemia is the limiting factor for glycemic control. Euglycemia is not glycemic goal in treatment of type1 diabetes but the goal is lowest mean glycemia that may not cause severe Hypoglycemia and allows continuous awareness of hypoglycemia.

Falling blood glucose level is a signal of series of response, includes decrease insulin secretion as glucose level is low and increase in glucogan, Epinephrine secretion and produce more sympathoadrenal response with glucose level 50 to 55mg/dl more recent reports shows that 6% to 10% of death in people with T1DM, are due to hypoglycemia.

According to American diabetes association (ADA) Hypoglycemia defined in Ty I DM patient, “Every episode of abnormal low plasma glucose concentration that exposes the potential harm to the

individual that include both symptomatic and asymptomatic hypoglycemia’’.

ADA (American Diabetic Association) also classifies the hypoglycemia as follows.

1. **SEVERE HYPOGLYCEMIA**

   Severe hypoglycemia is defined as a hypoglycemic episode that need another person to increase the blood glucose level and neurogenic recovery.

2. **DOCUMENTED SYMPTOMATIC HYPOGLYCEMIA**

   This is defined as an episode of hypoglycemia that is not associated with characteristic symptoms of hypoglycemia but with a finding of blood glucose level less than 70 mg/dl.

3. **ASYMPTOMATIC HYPOGLYCEMIA**

   This is defined as without any symptoms, only low blood glucose level.

4. **PROBABLE SYMPTOMATIC HYPOGLYCEMIA**

   This is an episode of hypoglycemia in which characteristic symptoms of hypoglycemia are not accompanied by a blood glucose level determination but symptoms were presumably because of blood glucose level less than 70 mg/dl

5. **RELATIVE HYPOGLYCEMIA**.

PRIMARY PREVENTION OF TYPE 1 DIABETES

A safe, effective, inexpensive, easy intervention could be theoretically targeted to all new born, but still now there is no universally accepted method. But delaying the introduction of cow's milk and cereals and prolonging the duration of breast feeding all methods are potentially beneficial trials and interventions are going. In high risk group people, especially with high risk genotype, parenteral and nasal insulin are proved equally not effective to prevent the diabetes but oral insulin appear to delay in incidence of diabetes in some patients, trials are currently going on .

SECONDARY PREVENTION

Type 1 DM is a T cell mediated immunity, start from 3 to 5 years before appearance of the clinical disease and continue after the diagnosis of TYPE 1 DM and effector mechanism is the cause for destruction of beta cell, involve cytotoxic T cells and soluble T cell products. Depending on the age 20 % TO 40% of beta cells are intact at the time of diagnosis and 1% of beta cells secretes even after 30 years of diagnosis This process lead to possibility of diabetes can be cured and ameliorated by stopping the auto immune destruction after initial diagnosis of type 1 diabetes (secondary prevention).

REVIEW OF LITERATURE

1.Irentibierg et al[9]. conducted a randomized control study in 117 newly diagnosed type 1 diabetes mellitus patients, aged 3 to 15 years. They compared the two groups Hospital Based Home care(HBHC)group, Hospital based care group. In HBHC group, HB A1 C levels were slightly higher but the mean value of parent satisfaction was higher, mean value of hospital stay lower and health care cost was 30 % lower. Further HBHC children showed lower mean glucose value and lower variable than in hospital based group. Fewer episodes of hypoglycemia were noted in HBHC group when compared to hospital based group. (significant p value < 0.001). After one month of trial they concluded that HBHC group as being a safe and cost effective way to make available the care in non ill patients.

2.Subishpalaian and Leelavathy[10] conducted study about knowledge, attitude, and practice and outcome of evaluating the impact of counseling in Hospitalized diabetic patients in India. In total 46 patients 27 were in control group and 19 patients in test group in diabetic specialized kasturiba hospital from November 2002 to April 2003. They counselled about the diabetes and life style modification in terms of knowledge, attitude, and practice at bed side over 60 minutes and sharing of leaflet till the hospital stay and review after 2 months at

fixed intervals. In this study to evaluate the consequence of the counseling in diabetic patients done by pharmacist and concluded that, counseling improves the knowledge but not the attitude and practice. The limitation of the study is that it did not to evaluate the compliance of diabetic patients and study group is tiny.

3.Berhave seyoum et al[11]. conducted a descriptive study in department of internal medicine, Addis Ababa university, Ethiopia. He enrolled 100 diabetic patients who were on insulin therapy and observations shown 53 patients had Hyper pigmentation at injection site and 30 patients had indurations and 31patients had hypertrophy .

He concluded that illiteracy was considerably associated with local site complication (p value < 0.05), and also fasting blood glucose mean value is high (p value <0.001) in patient without local complications . He did not find any disproportion in the duration of diabetes , frequency of hypoglycemic episodes(p value > 0.05) and also this study concluded that local site complication result from incorrect technique and disfigurement may compromise the compliance, so that inspection of the injection site is often needed to detect and correct the defective technique .

4.De Villiers et al[12]. conducted a descriptive study in department of pediatrics and child health university of Limbobo. He included 23

diabetic patients of different age group from 6 to 18 years old, to see the prevalence of lipohypertropy in pediatric diabetic patients. He found significant correlation between lipohypertropy and number of visits for review. He also found that 52% of diabetic patients had lipohypoypertropy and 80 % patients among them are frequently examined for lipohypertropy.. It does not occur in first year of diabetic life, in 50% of the patients developed during the 2^{nd} year and 30 % patients developed on the 5^{th} year .Finally he concluded that lipohypertropy is not easy to recognize, it needs wide-ranging education. Identification of lipohypertropy need physical examination by palpation, not only by inspection.

5. Christopher f. jasinki and Rosa Rodriguez-monguio[13] conducted a retrospective cross-sectional study including 84 patients in age group 1to 18 years from the Baystate hospital for children to evaluate the metabolic outcome, health care utilization and cost in type1diabetic patients comparing those educated in hospital based group and who are all treated in outpatient group.

He found that the average health care utilization of the inpatient group is 2.6 higher than that of outpatient (group p value <0.001), the average charge for diagnostic test for in patients were significantly higher

in inpatient group than outpatient group and there is no major difference of mean value of HBA_1C in both the group.

The limitation of this study is potential of selection bias which is common in all non randomized control study and this study concluded that with hospital admission for type 1 diabetic care and learning , insulin management training in new onset of diabetes patients who are non critically ill does not result in better metabolic outcome during the first year of post diagnosis.

STUDY JUSTIFICATION

Not much literature exists on home based insulin therapy in children with type1 diabetes from India. Also there are limited support groups for children with type1 diabetes. Children from lower socio economic group have limited access to frequent blood glucose monitoring, and frequent counseling session for regular therapy, unless they attend the center with facilities for pediatric diabetic care. In this scenario, we decided to evaluate the home based insulin therapy related problems and the impact of repeated counseling session in rectifying the same.

The outcome of the study may help to evaluate the usefulness of counseling package used and also help to revise the counseling frequencies at diabetic clinic.

OBJECTIVES OF THE STUDY

- To assess the problems of home based insulin therapy in type1 diabetic children less than 12 yrs.

- To assess the impact of repeated counseling on correction of errors during the home based insulin therapy.

METHODOLOGY

STUDY DESIGN : Descriptive study

STUDY PLACE : Diabetic clinic and medical wards of ICH

STUDY PEROID: Protocol formulation - August 2013 to October 2013

Data collection - October2013 to July 2014

Data analysis and - Aug 2014 to September 2014

Manuscript preparation:

Submission of report - October 2014

STUDY POPULATION:

Inclusion criteria

All diabetic children more than 1 year within 18 months of diagnosis, attending the diabetic clinic of ICH / admitted in ward within study period.

Exclusion criteria

None.

Sample size

All children satisfying inclusion criteria attending diabetic clinic in the specified period.

STUDY MANEUVER

All children satisfying inclusion criteria were recruited from diabetic clinic OPD and wards in ICH, Egmore. Children recently diagnosed to have diabetes in the past 18 months were recruited. Age, gender, diabetic age, caregiver or parental educational status was recorded in the prescribed proforma.

Initial evaluation was done to assess the technique of home based insulin therapy. Evaluation covers the following parameters

1) Loading of insulin
   - ❖ Order of loading
   - ❖ accuracy of the dose

2) Injection technique
   - ❖ Pre skin cleaning
   - ❖ Appropriate skin pinch
   - ❖ Needle angle

3) Limb rotation

4) Site rotation

5) Disposal of syringe

6) Local site complication and the level of diabetic control

Once the baseline data were collected, the child's care giver was to undergo the counseling package in the form of oral and video demonstration.

All the children were provided the glucometer, glucometer strips, insulin, and insulin syringe in the diabetic clinic. They were followed up in 2 visits at 3 months interval.

At each schedule visit, the injection procedure was observed for any errors, data recorded, followed by counseling session and blood was drawn for HBA_1C estimation. The same process was repeated on each visit.

ETHICAL CONSIDERATIONS

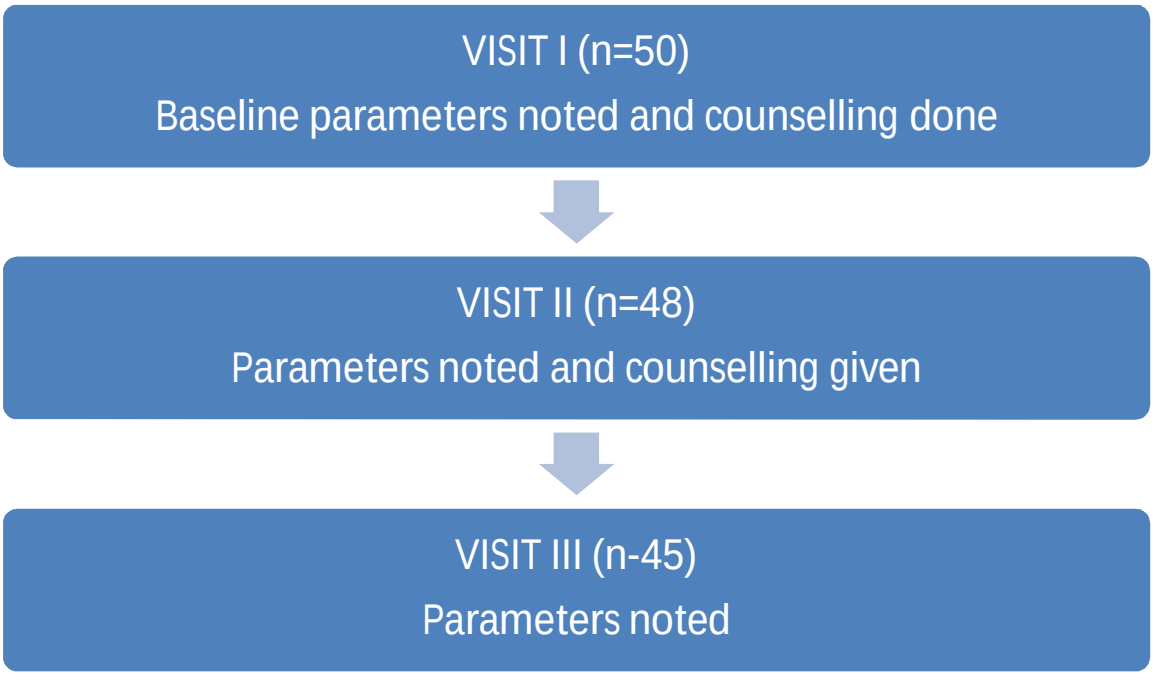
Ethical clearance was obtained prior to starting the study. Every patient was included in the study after obtaining informed consent from the parent. Strict confidentiality of data was maintained throughout.

STATISTICAL ANALYSIS

Data was entered in excel sheet. Qualitative variables were expressed as proportion; quantitative variables were converted into categories and again expressed in proportion. The change of all parameters before and after counseling was analyzed using chi–square test. Statistical significance was considered when the p value was <0.005.

RESULTS

Total of 50 patients were included in this study and came for the first visit ,out of which 48 patients came for the second visit and only 45 patients attended third visit.



Overall the follow up rate was 90%.

TABLE : 1

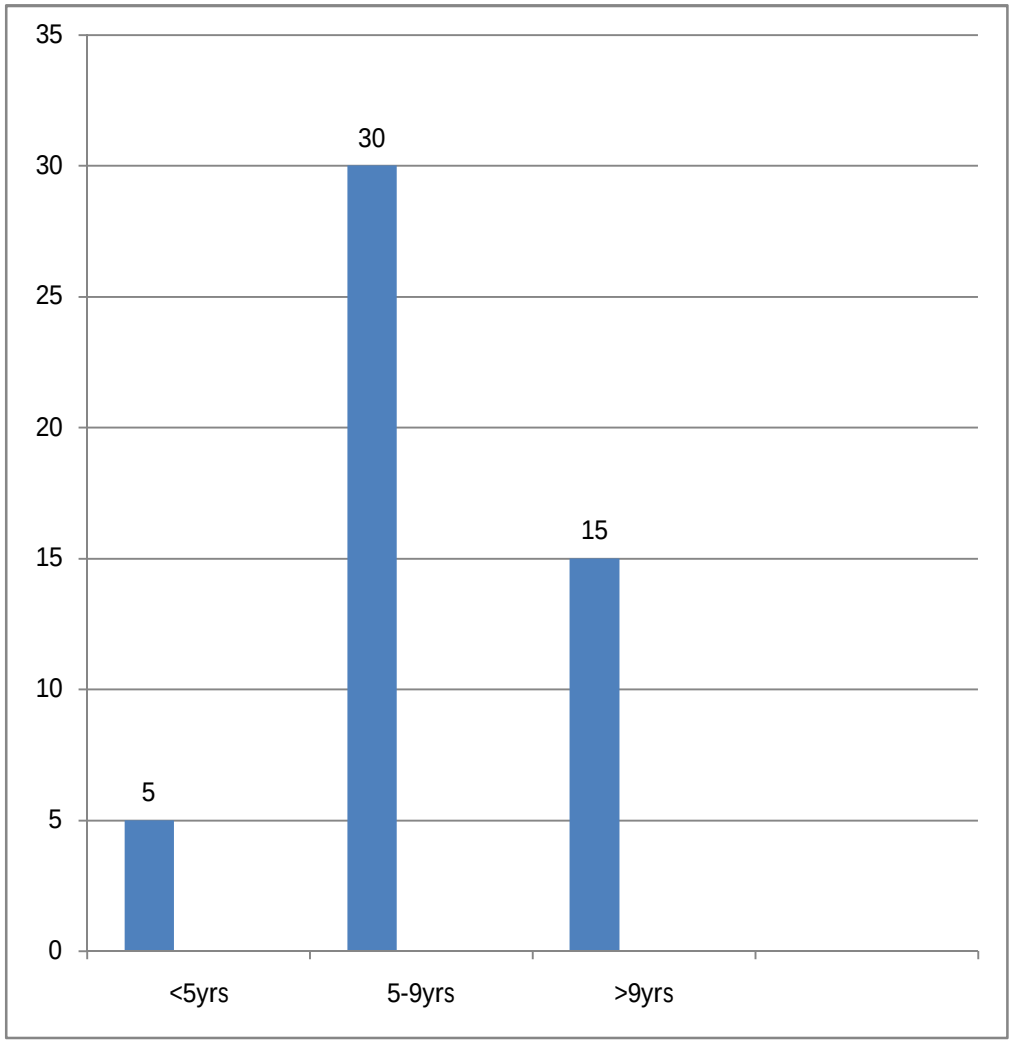
AGE DISTRIBUTION

Age category	Frequency	Percentage
< 5 years	5	10 %
5-9 years	30	60 %
> 9 years	15	30 %
Total	50	100 %

Most common age group recruited in this study was 5 to 9 years, which constitutes 60 % followed by >9years who constituted 30% while children <5 years of age constituted the minimum, i.e. 10%.

CHART : 1

AGE DISTRIBUTION



This chart shows the age group distribution in the study.

TABLE : 2

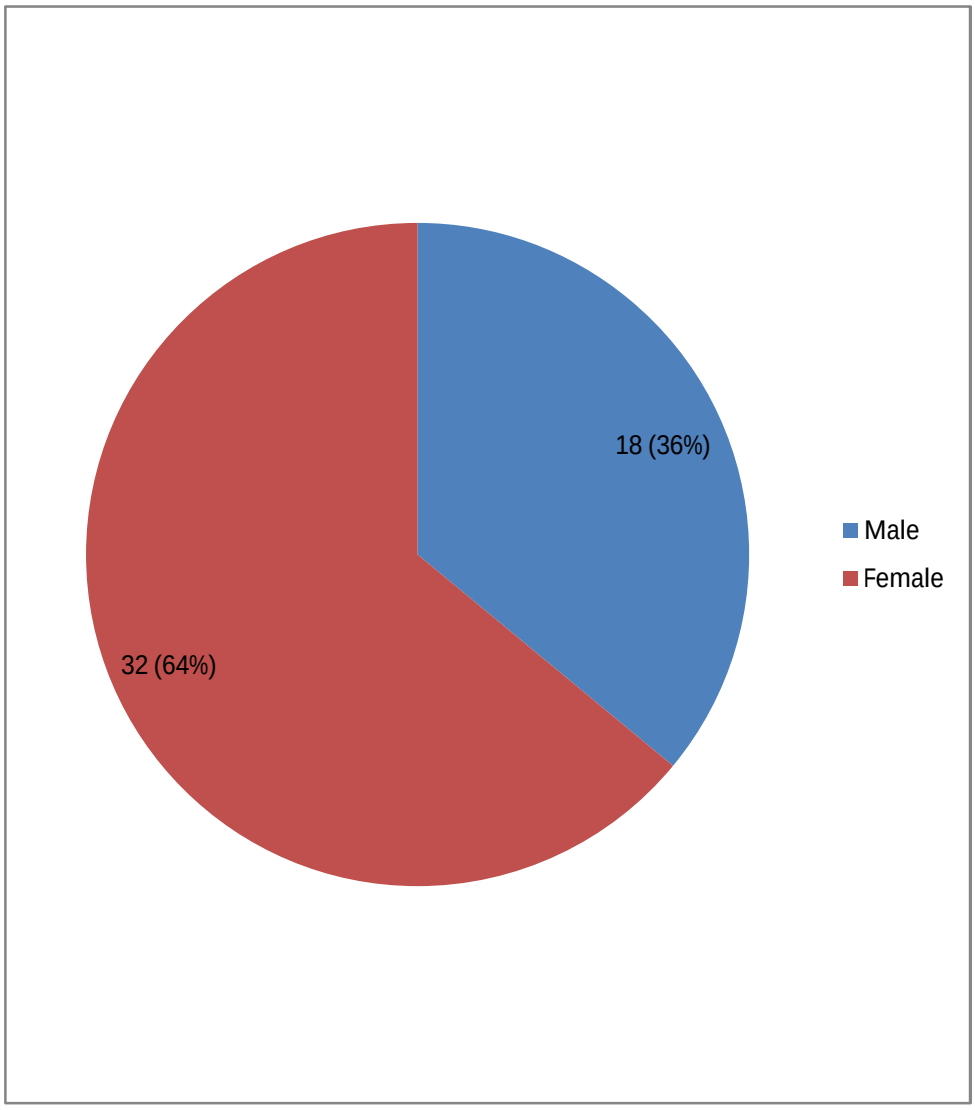
GENDER DISTRIBUTION

Sex	Frequency	Percentage
Male	18	36 %
Female	32	64 %
Total	50	100 %

In this Study there were more patients in female sex than male sex, 64% as against 36%.

CHART : 2

GENDER DISTRIBUTION - CHART



This pie chart shows the gender distribution of patients in this study.

TABLE : 3

BODY MASS INDEX

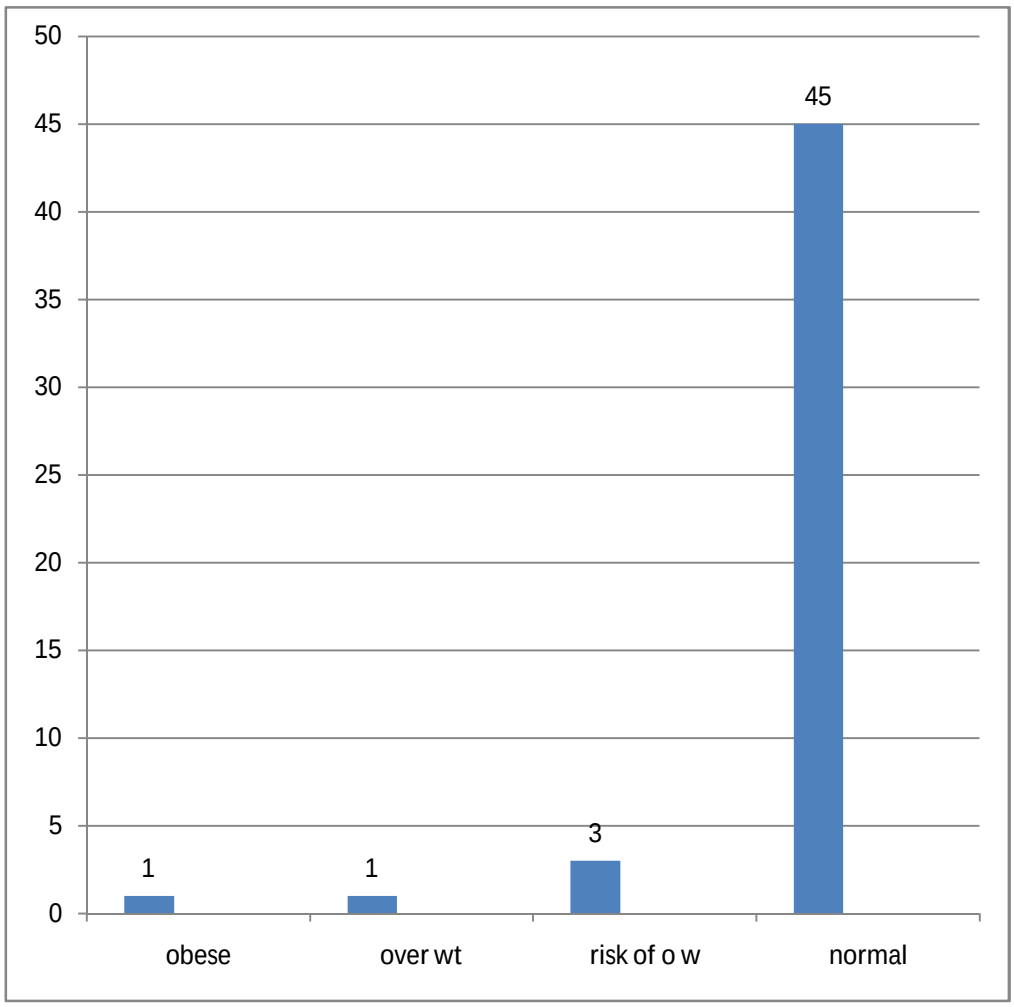
BMI category	Frequency	Percentage
Obese	1	2.0 %
Over Weight	1	2.0 %
Possible Risk of Over Weight	3	6.0 %
Normal	45	90.0 %
Total	50	100.0 %

This table shows the body mass index of children involved in this study.

Most children (90%) have normal body mass index, followed by possible risk of overweight which is 6% percentage. Only 2% of children fall in overweight and obese category. None of the children were in under nutrition category.

CHART : 3

BODY MASS INDEX - CHART



This chart shows the diagramatic representation of BMI category.

TABLE : 4

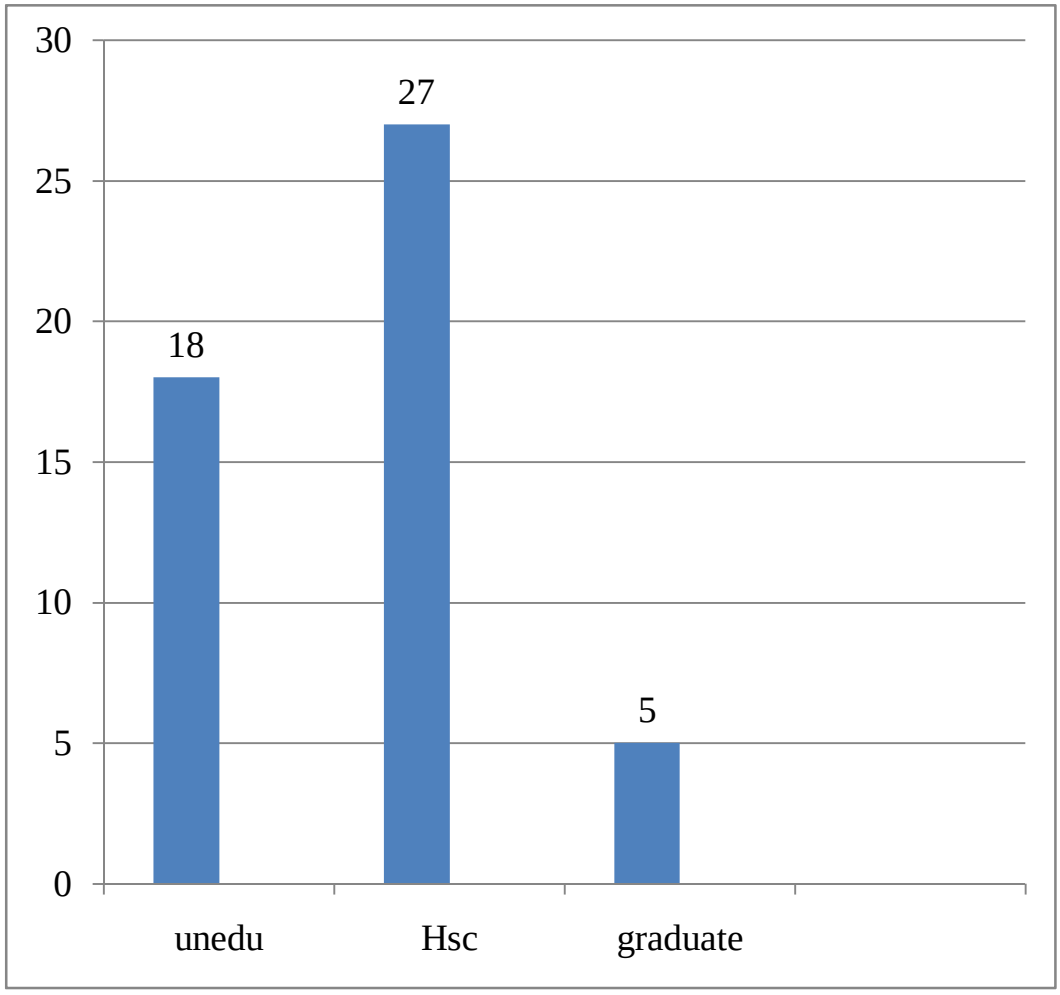
PARENTAL EDUCATION DISTRIBUTION

Education level	Frequency	Percentage
Uneducated	18	36.0 %
Upto HSc	27	54.0 %
Graduate	5	10.0 %
Total	50	100%

Parents of maximum number of children (54%) had completed their education upto higher secondary level. 36% were uneducated and 10% were graduates.

CHART : 4

PARENTAL EDUCATION



Given above is graphical depiction of parents' educational status.

TABLE : 5

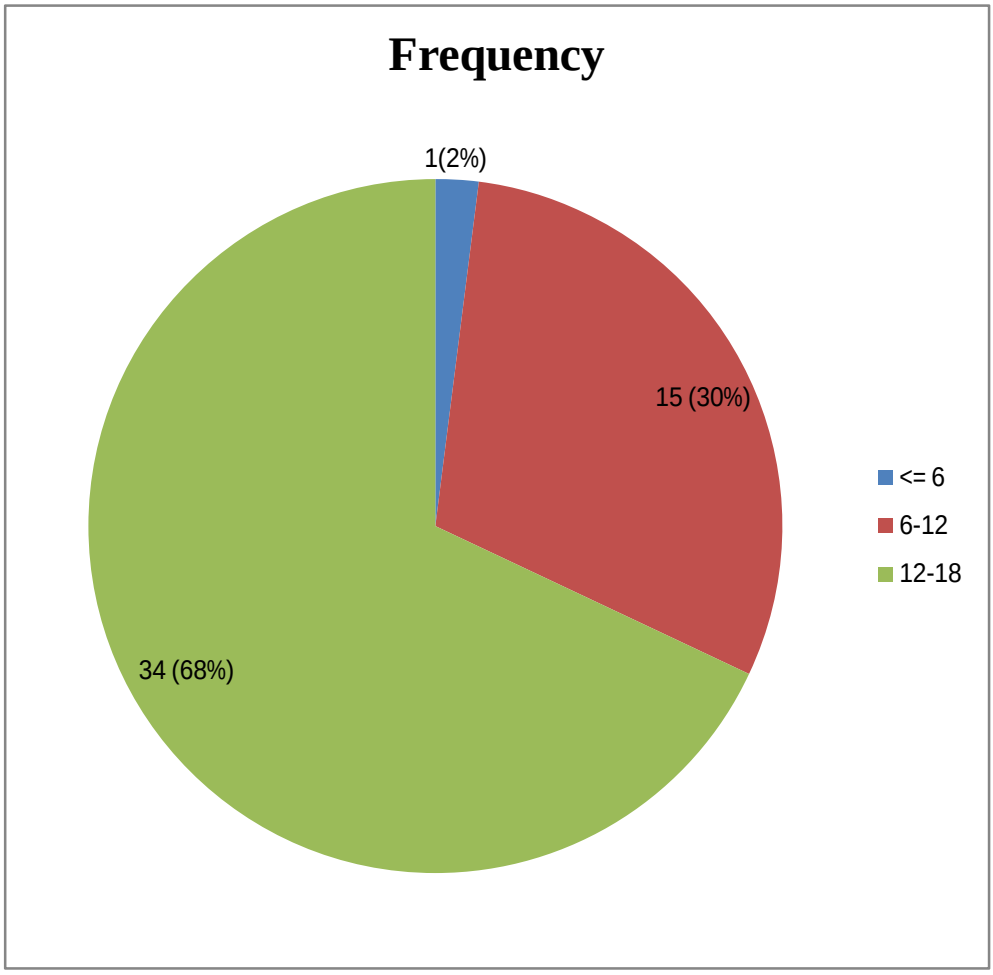
DURATION OF ILLNESS

Duration of illness (months)	Frequency	Percentage
<= 6	1	2.0 %
6-12	15	30.0 %
12-18	34	68.0 %
Total	50	100.0 %

Maximum children (68%) were diagnosed to have diabetes between 12 and 18 months, followed by 6-12 months (30%) and <6 months (2%).

CHART : 5

DURATION OF ILLNESS



This is a diagramatic distribution of duration of illness -In this study.

TABLE : 6

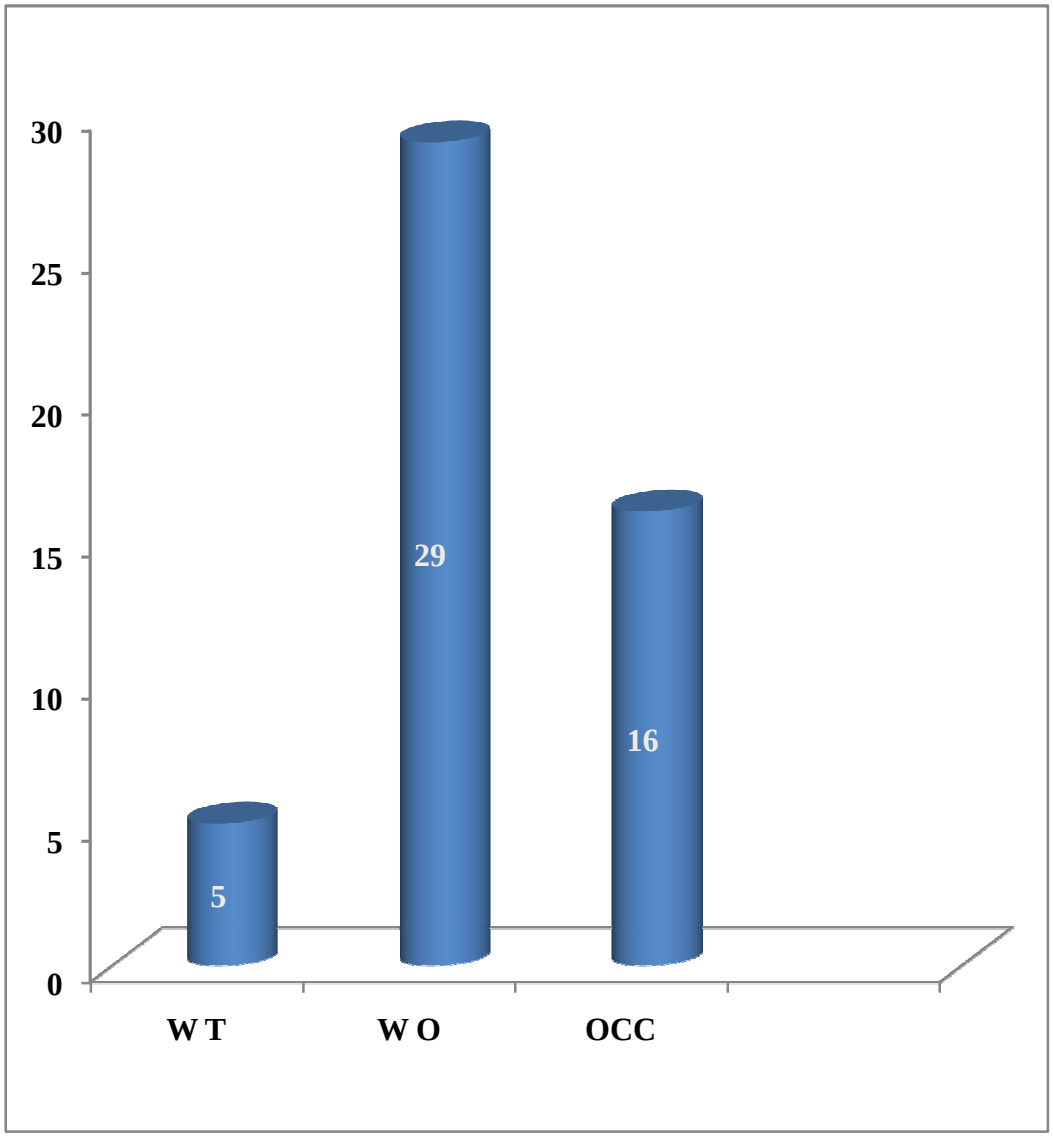
SMBG – I VISIT

SMBG frequency	Frequency	Percentage
Weekly Twice	5	10 %
Weekly once	29	58 %
Occasional	16	32 %
Total	**50**	**100 %**

This table shows that self monitoring of blood glucose was done weekly twice only in 10 % of patients, weekly once in another 58% and only occasionally in rest 32% which is very sub optimal.

CHART : 6

SMBG - I VISIT - CHART



This is diagramatic representation of SMBG frequency - In this study.

TABLE : 7

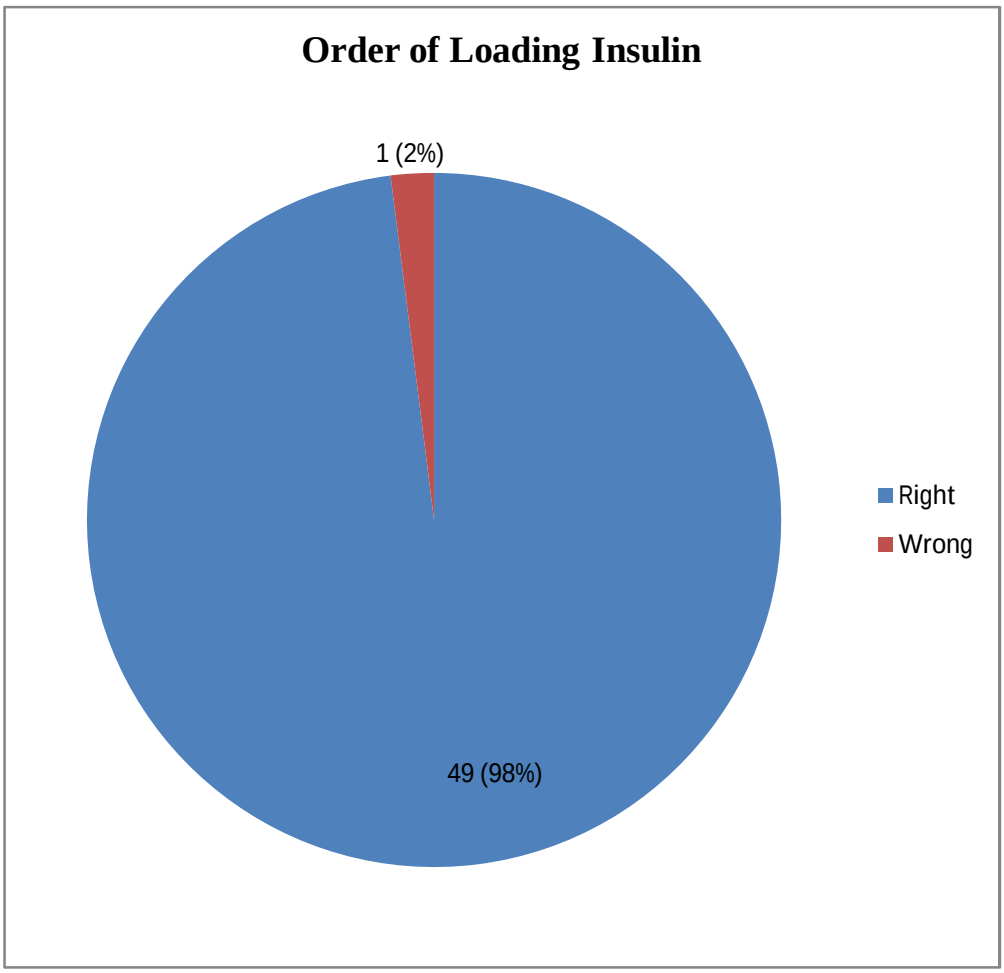
LOADING OF INSULIN – I VISIT

Method of loading	Frequency	Percentage
Right	49	98%
Wrong	1	2%
Total	50	100%

98 % of parents were correct in the order of loading of insulin on their first visit.

CHART: 7

LOADING OF INSULIN – I VISIT



This is diagramatic representation of Loading of Insulin – I Visit - In this study.

TABLE : 8

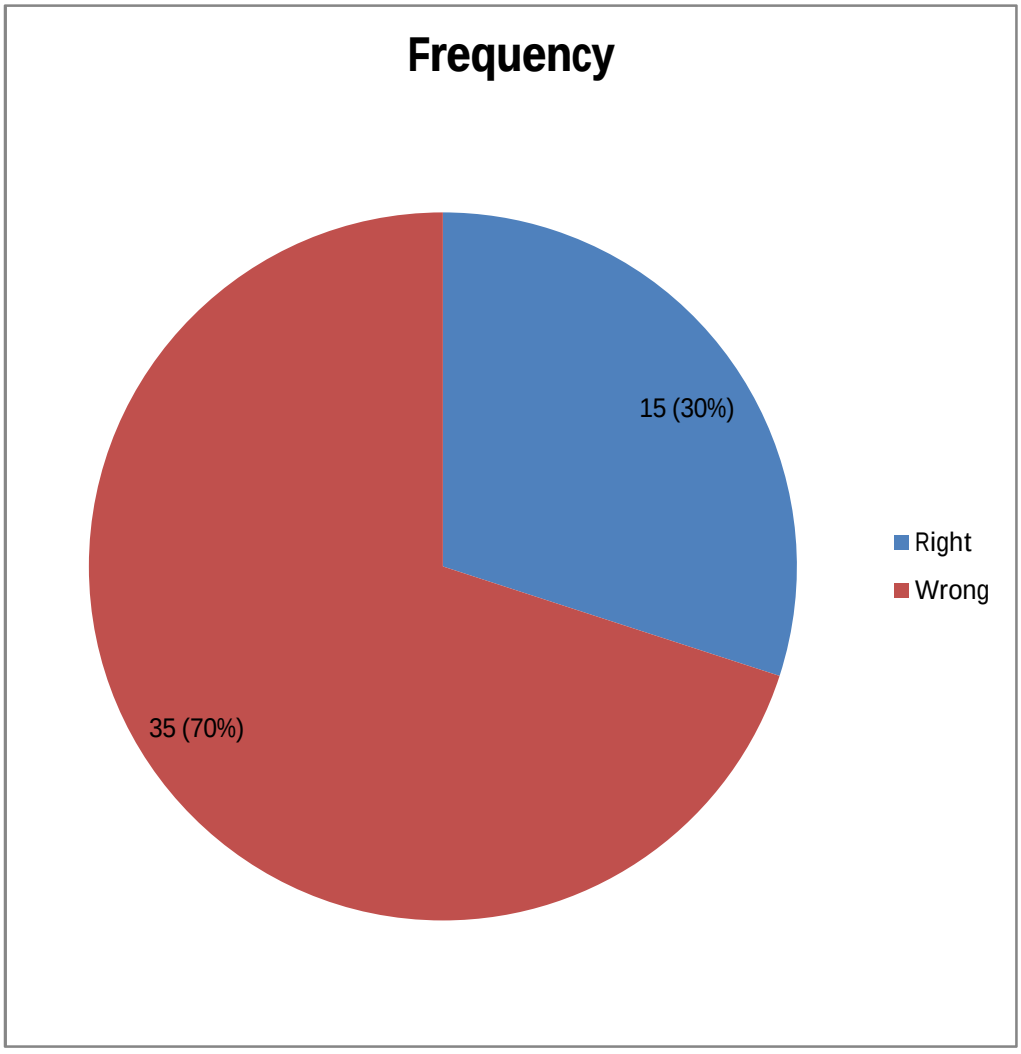
ACCURACY OF DOSE INSULIN – I VISIT

Accuracy of dosage	Frequency	Percentage
Right	15	30%
Wrong	35	70%
Total	50	100%

The accuracy of insulin dose loaded was correct only in 30% on first visit while majority (70%) were inaccurate in loading the correct dosage.

CHART : 8

ACCURACY OF DOSE INSULIN – I VISIT



This is diagramatic representation accuracy of dose Insulin – I visit.

TABLE : 9

PRE INJECTION CLEANING –I VISIT

Pre injection cleaning	Frequency	Percentage
Done	4	8%
Not done	46	92%
Total	50	100%

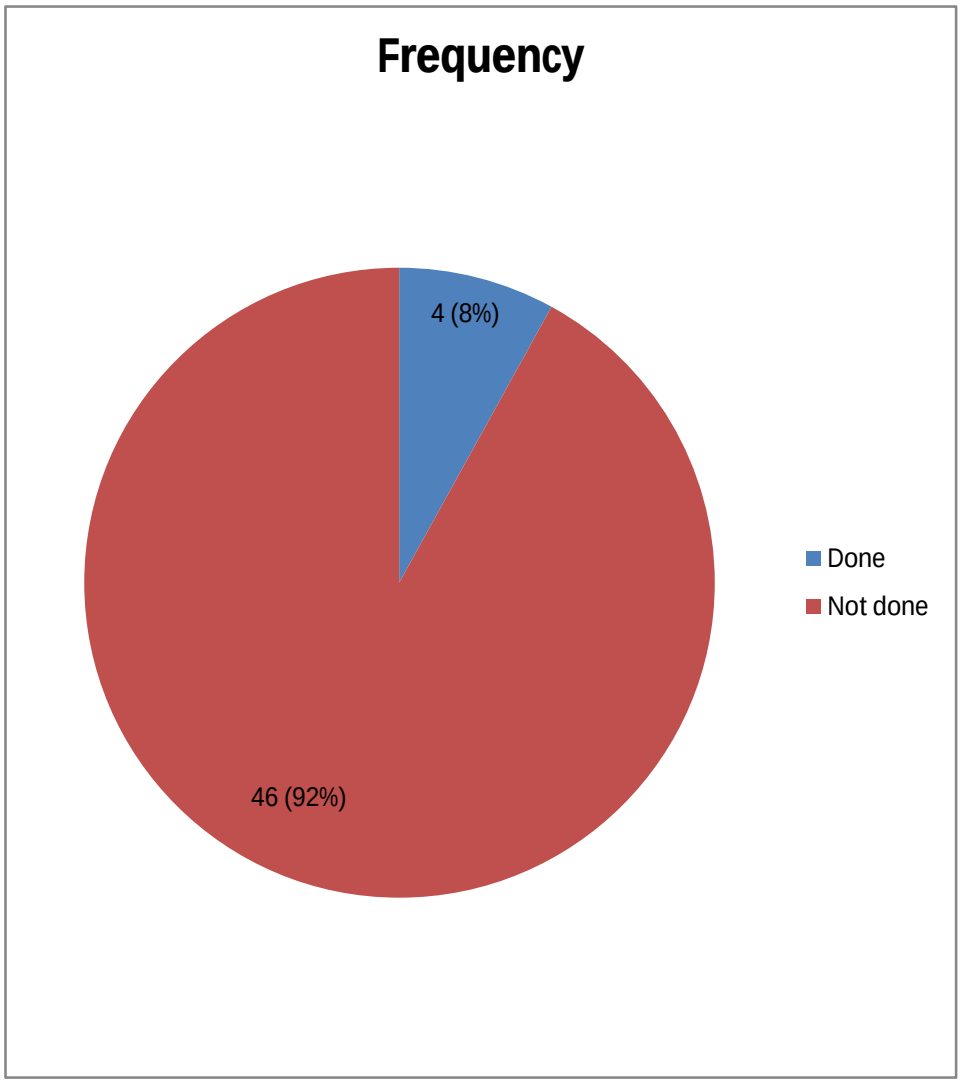
There is no need of any pre skin cleaning prior to insulin injection.

This was understood and practiced correctly by 92 % patients.

Pre skin cleaning, which was unwarranted was done in only 8%.

CHART : 9

PRE INJECTION CLEANING – VISIT I



This is diagramatic representation of Pre-injection cleaning - First Visit.

TABLE : 10

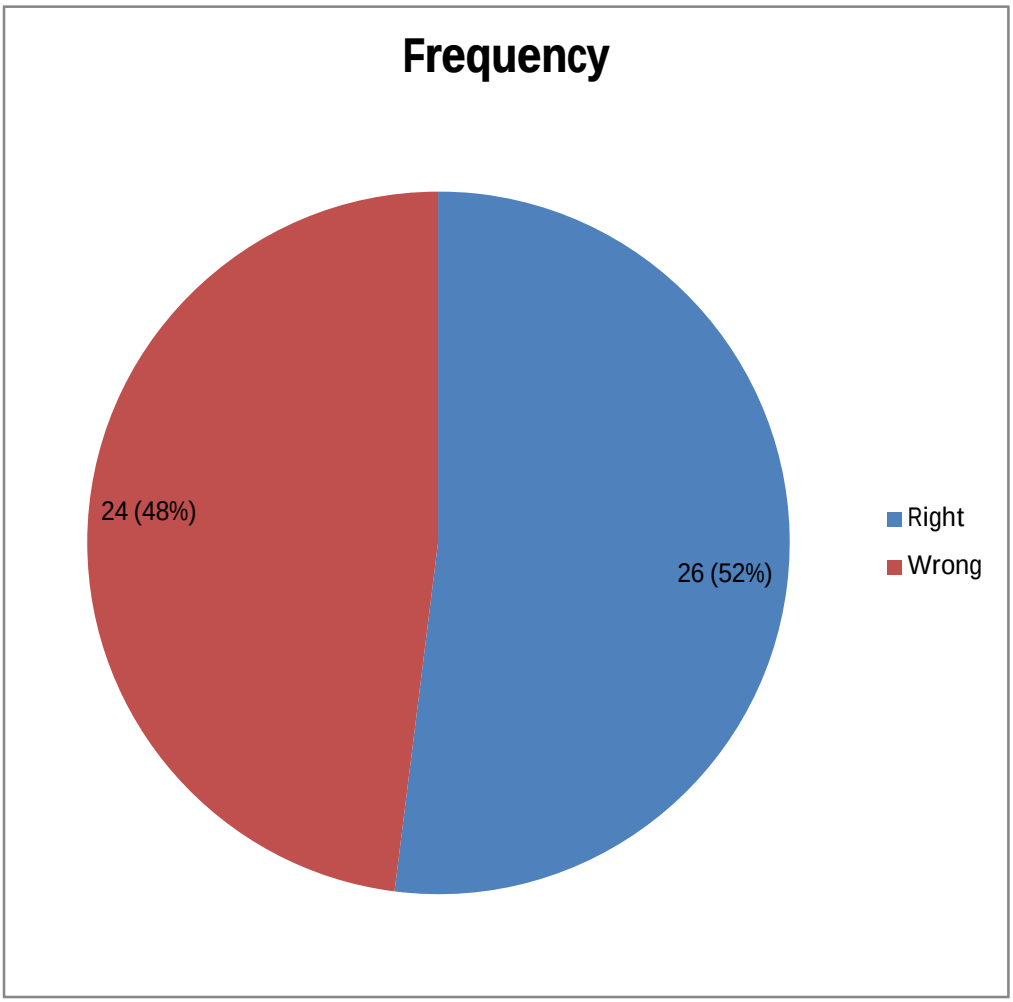
SKIN PINCH – I VISIT

Skin pinch	Frequency	Percentage
Right	26	52%
Wrong	24	48%
Total	50	100%

This table shows that skin pinch appropriation at the I visit was correct only in 52 % of patients. The other 48% patients were incorrect.

CHART : 10

SKIN PINCH – I VISIT



This is diagramatic representation of Skin Pinch - First Visit.

TABLE : 11

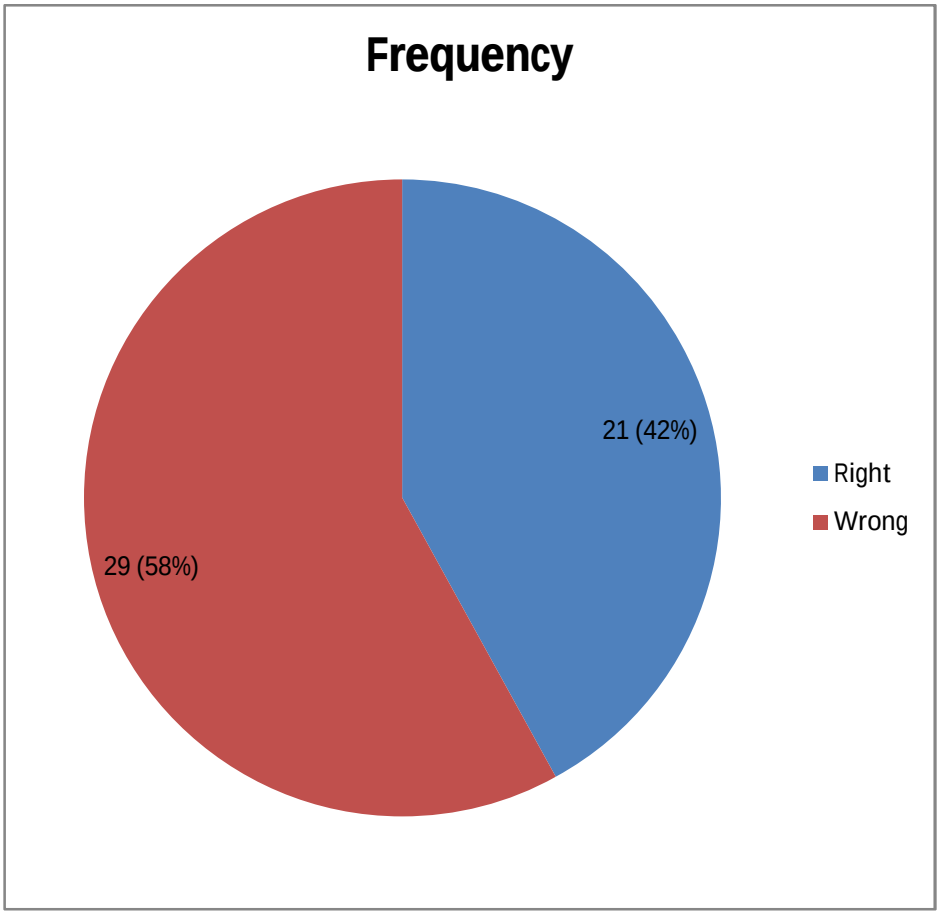
NEEDLE ANGLE – I VISIT

Needle Angle	Frequency	Percentage
Right	21	42%
Wrong	29	58%
Total	50	100%

This table shows needle angle was correct in only 42 % patients and incorrect in 52 % on first visit.

CHART : 11

NEEDLE ANGLE – I VISIT



This is diagramatic representation of Needle Angle - First visit.

TABLE : 12

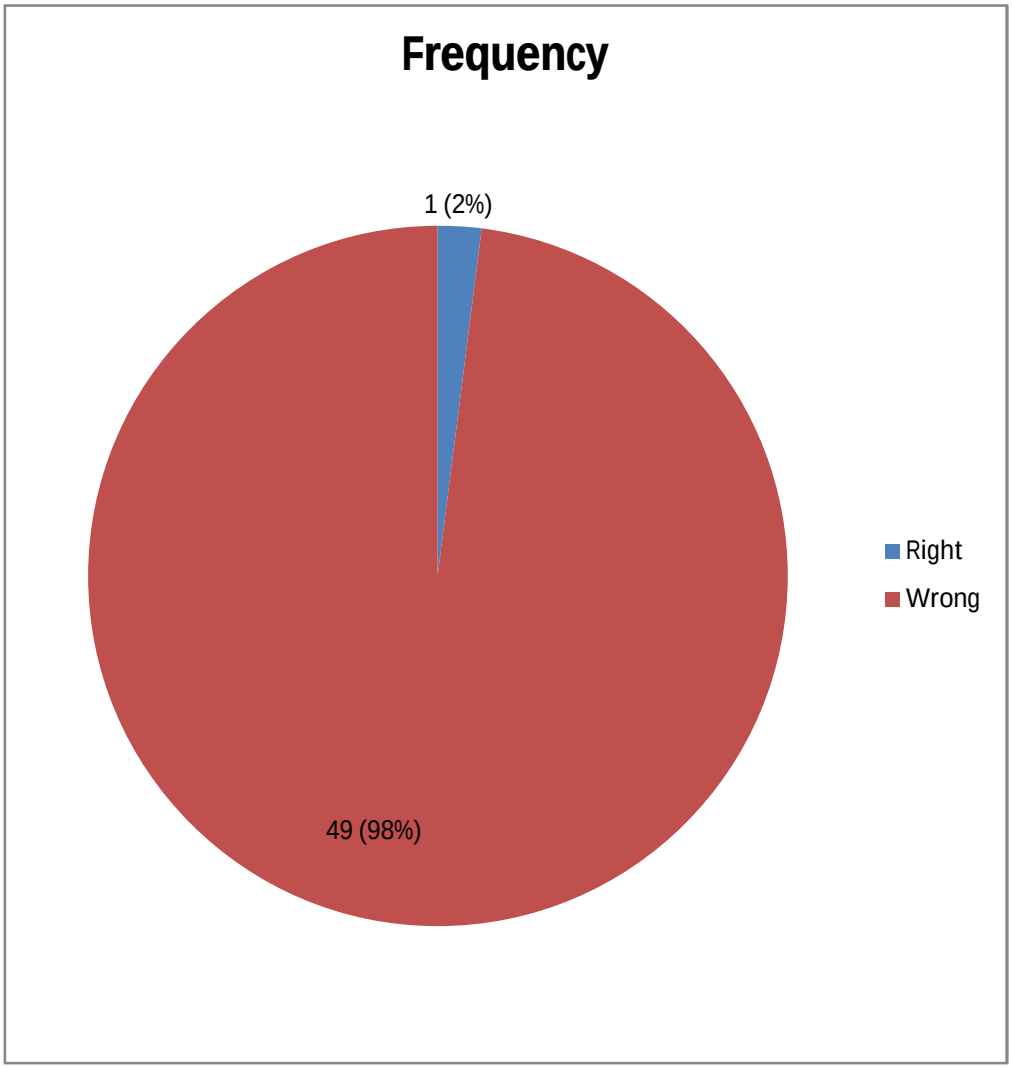
DISPOSAL OF SYRINGE – I VISIT

Syringe disposal	Frequency	Percentage
Right	1	2%
Wrong	49	98%
Total	50	100%

Disposal of syringe was done correctly only in 2% of patients while it was done wrongly by 98 % of patients.

CHART : 12

DISPOSAL OF SYRINGE – I VISIT



This is diagramatic representation of disposal of syringe - First visit.

TABLE : 13

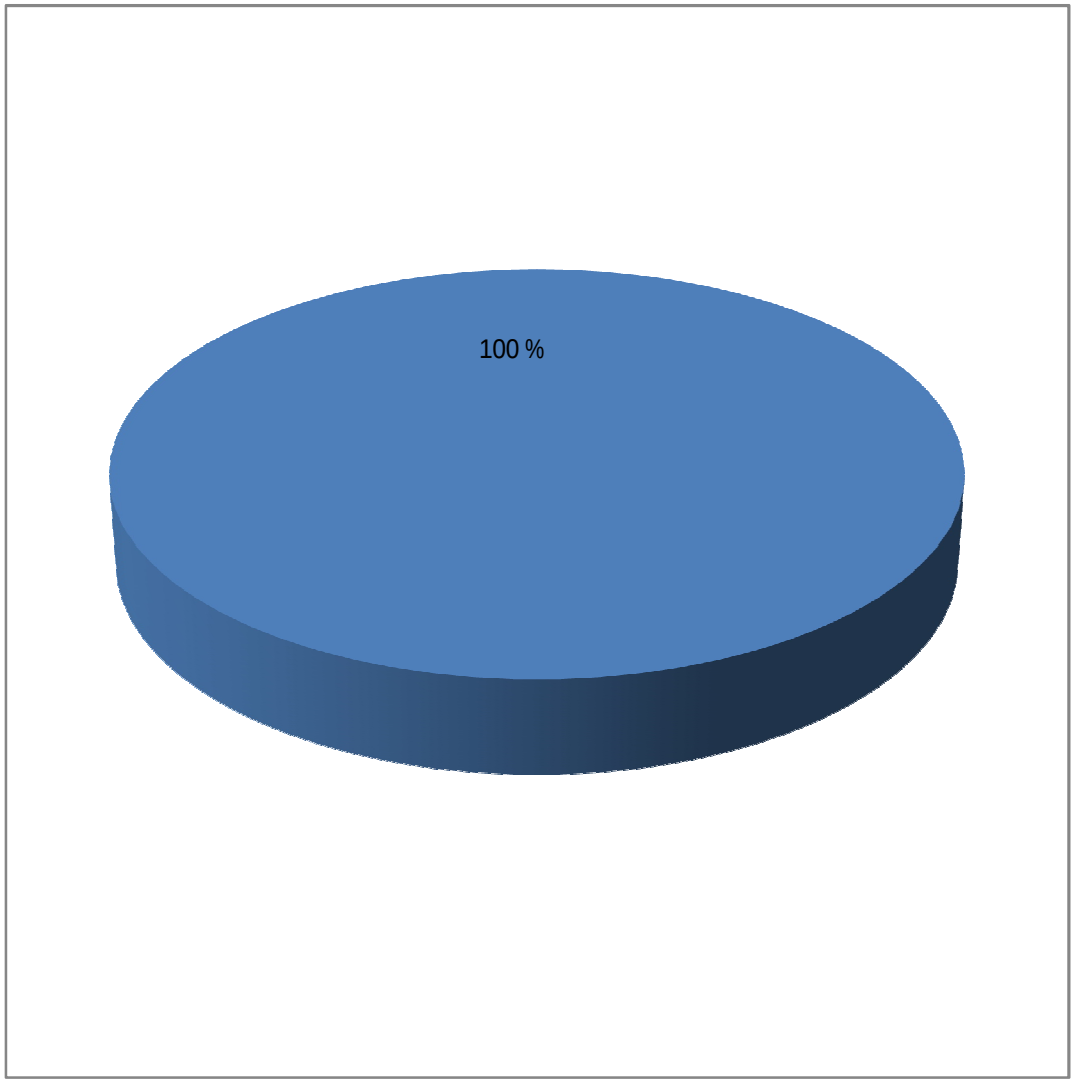
LIMB ROTATION – I VISIT

Limb rotation	Frequency	Percentage
Right	50	100%
Wrong	0	0%

This table shows that limb rotation was practiced correctly in all patients at first visit itself.

CHART : 13

LIMB ROTATION – I VISIT



This is diagramatic representation of LimbRotation in - First visit.

TABLE : 14

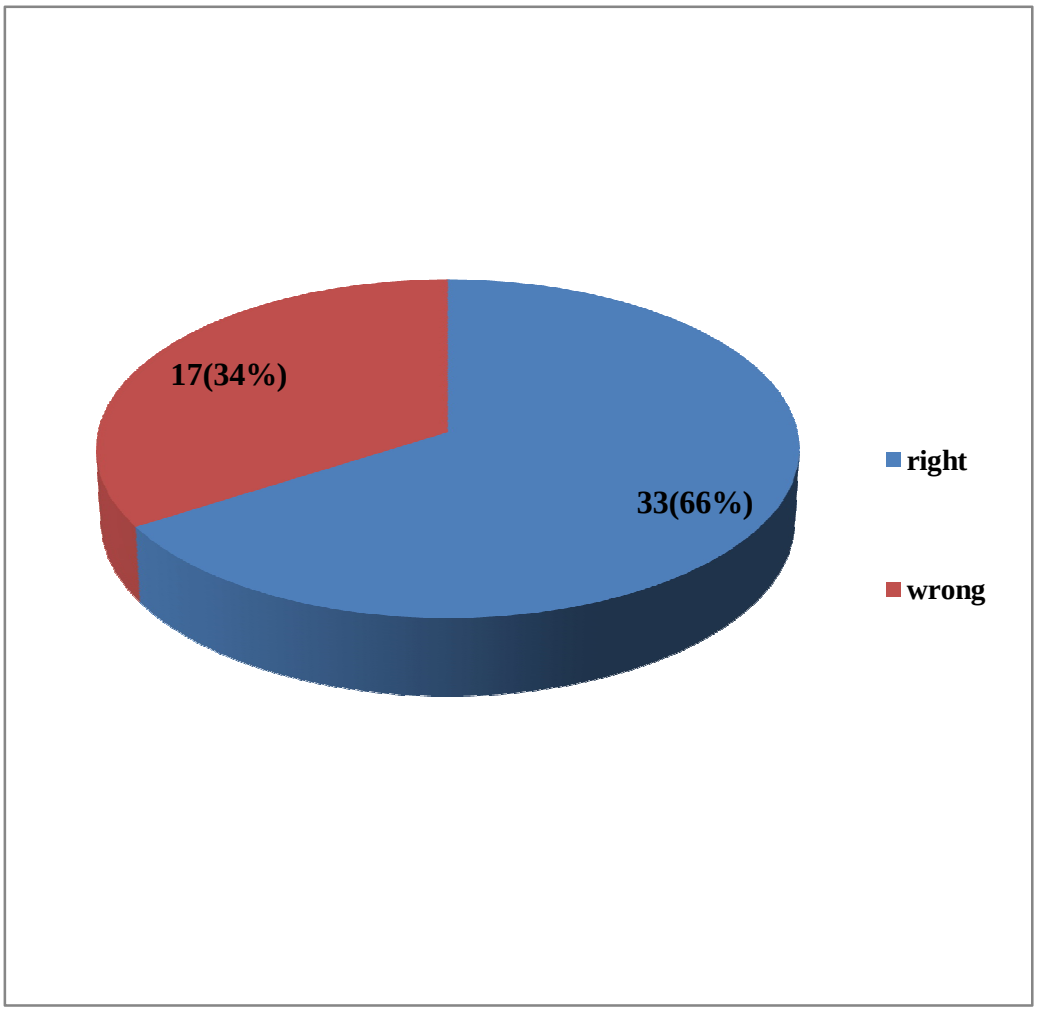
SITE ROTATION—I VISIT

Site Rotation	Frequency	Percentage
Right	33	66%
Wrong	17	34%

This table shows only 66% of patients rotated the injection site and other 34% did not.

CHART : 14

SITE ROTATION—I VISIT



This is diagramatic representation of Site Rotation in First visit.

TABLE : 15

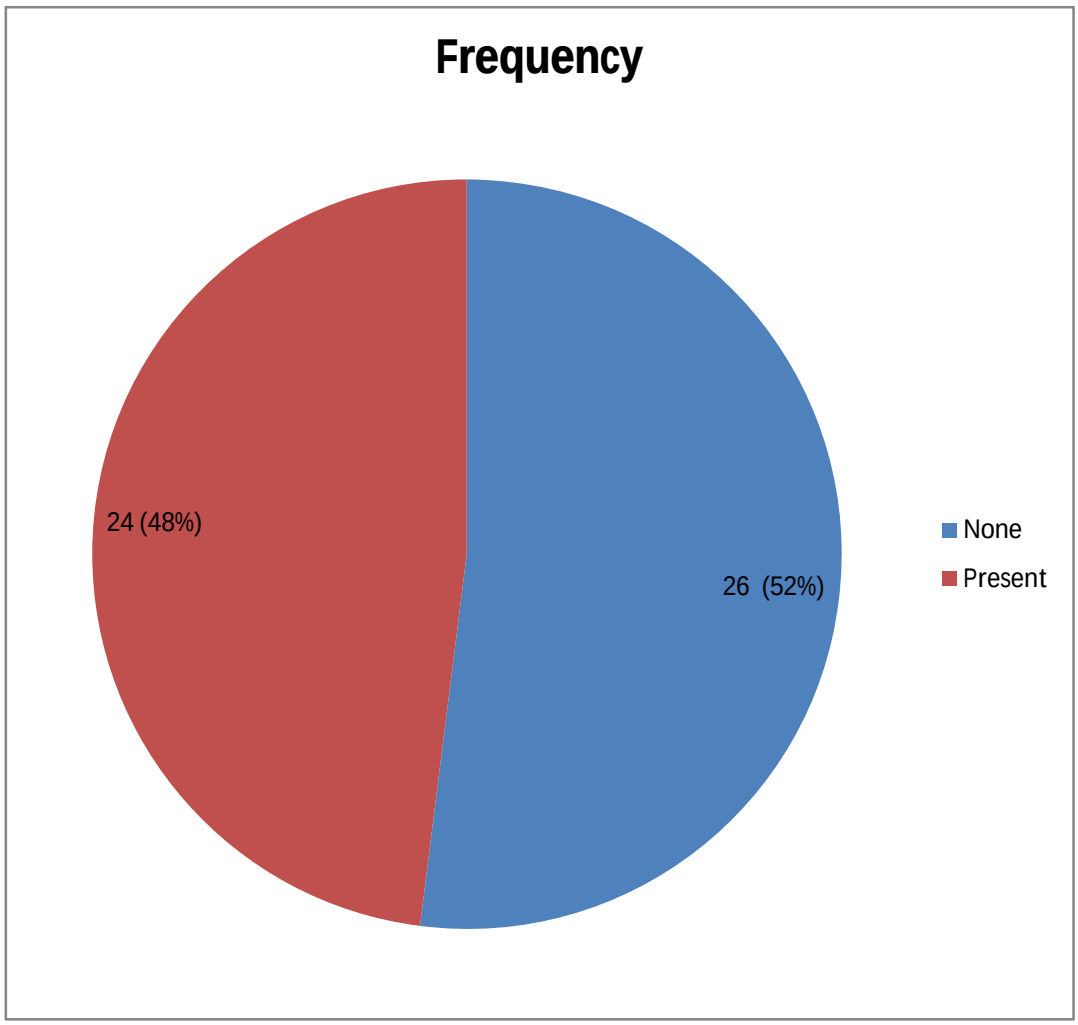
SITE RELATED PROBLEM - I VISIT

Site Problems	Frequency	Percentage
None	26	52 %
Present	24	48 %
Total	50	100 %

52 % of patients did not have any site related problem at first visit, but 48% of patients had these problems.

CHART : 16

SITE RELATED PROBLEM - I VISIT



This is diagramatic representation of Site Related problem in First visit.

TABLE : 17

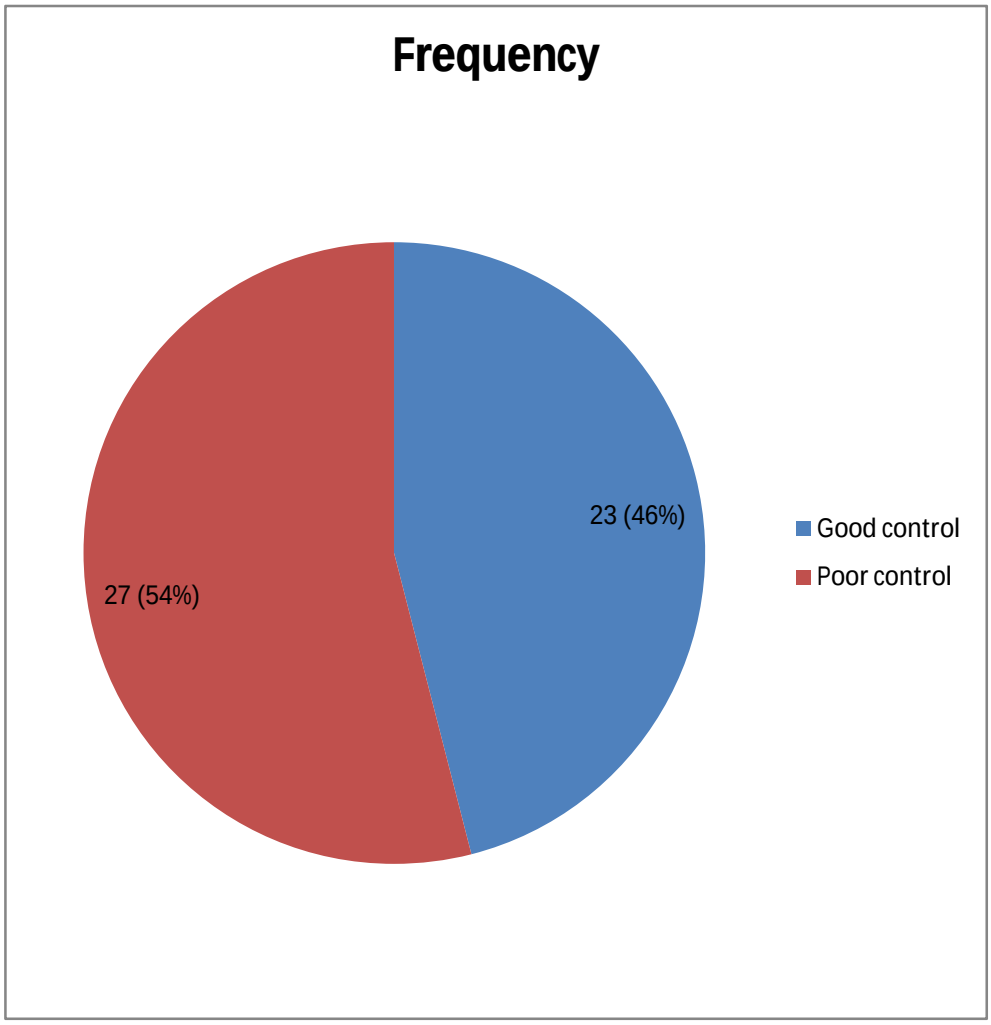
HbA_1C – I VISIT

HbA1c range	Frequency	Percentage
Good control	23	46 %
Poor control	27	54 %
Total	50	100 %

46 % Patients had HbA_1C levels within good control range while HbA_1C levels were outside the range in 54 % patients in first visit.

CHART : 17

HbA_1C – I VISIT



This is diagramatic representation of HbA_1C – I Visit.

TABLE : 18

EFFECT OF COUNSELLING ON PARAMETERS

SMBG – PRE AND POST COUNSELLING

SMBG Frequency	First visit	Second visit	Third visit
Weekly Twice	10%	33.3 %	46.7%
Weekly Once	58%	58.3%	53.3%
Occasional	32%	8.4%	0

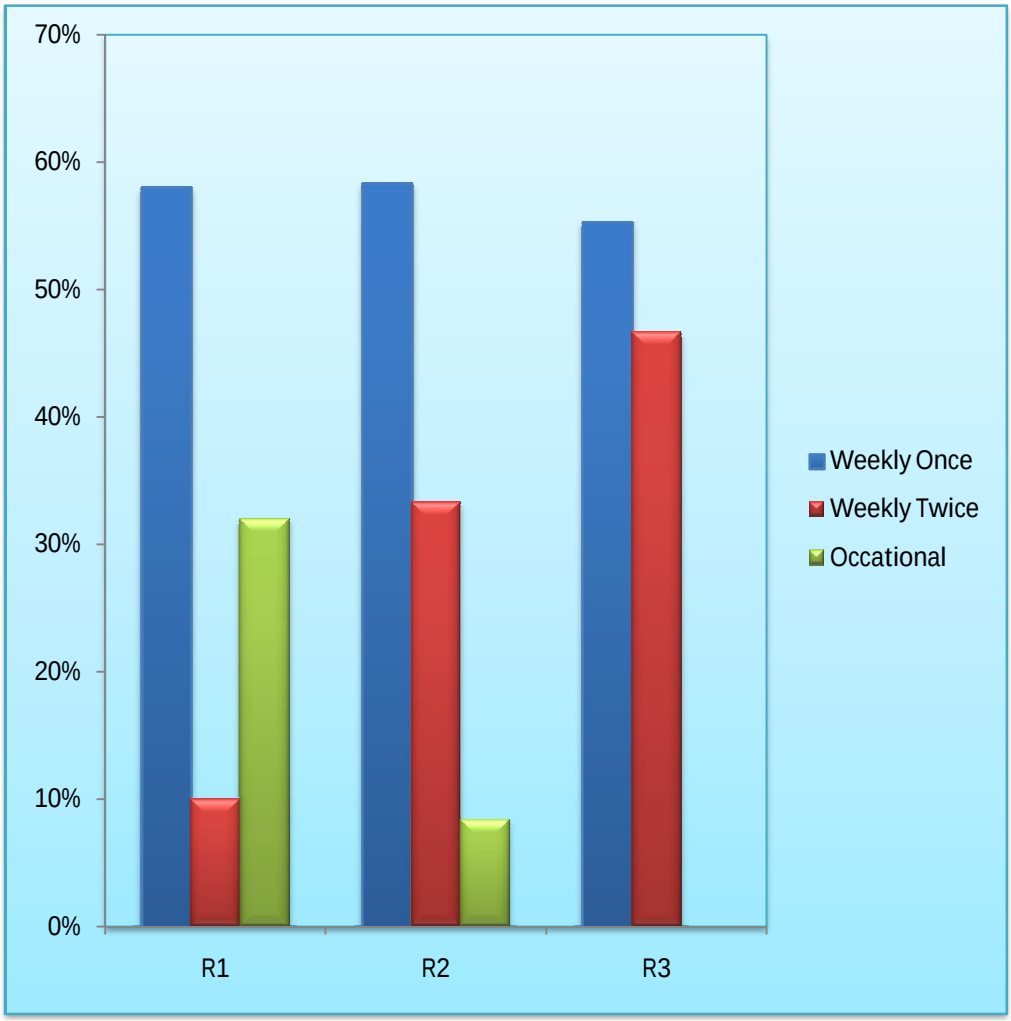
On first visit, SMBG was done weekly twice in only 10% and it increased to 33.3% in second visit after first counseling. This increase of 23.3 % was found to be statistically significant with a p value of 0.001.

After second counseling, on third visit there was a further increase of 13.4 % in SMBG frequency which was also statistically significant (p value 0.001).

Overall, after two counseling sessions, all patients who were performing SMBG sub optimally improved with 46.7% performing weekly twice, the rest 53.3% performing weekly once and none less frequently. This difference was also statistically significant.

CHART : 19

SMBG



This clustered bar chart clearly shows the improvement in frequency of monitoring SMBG in every visit.

TABLE : 20

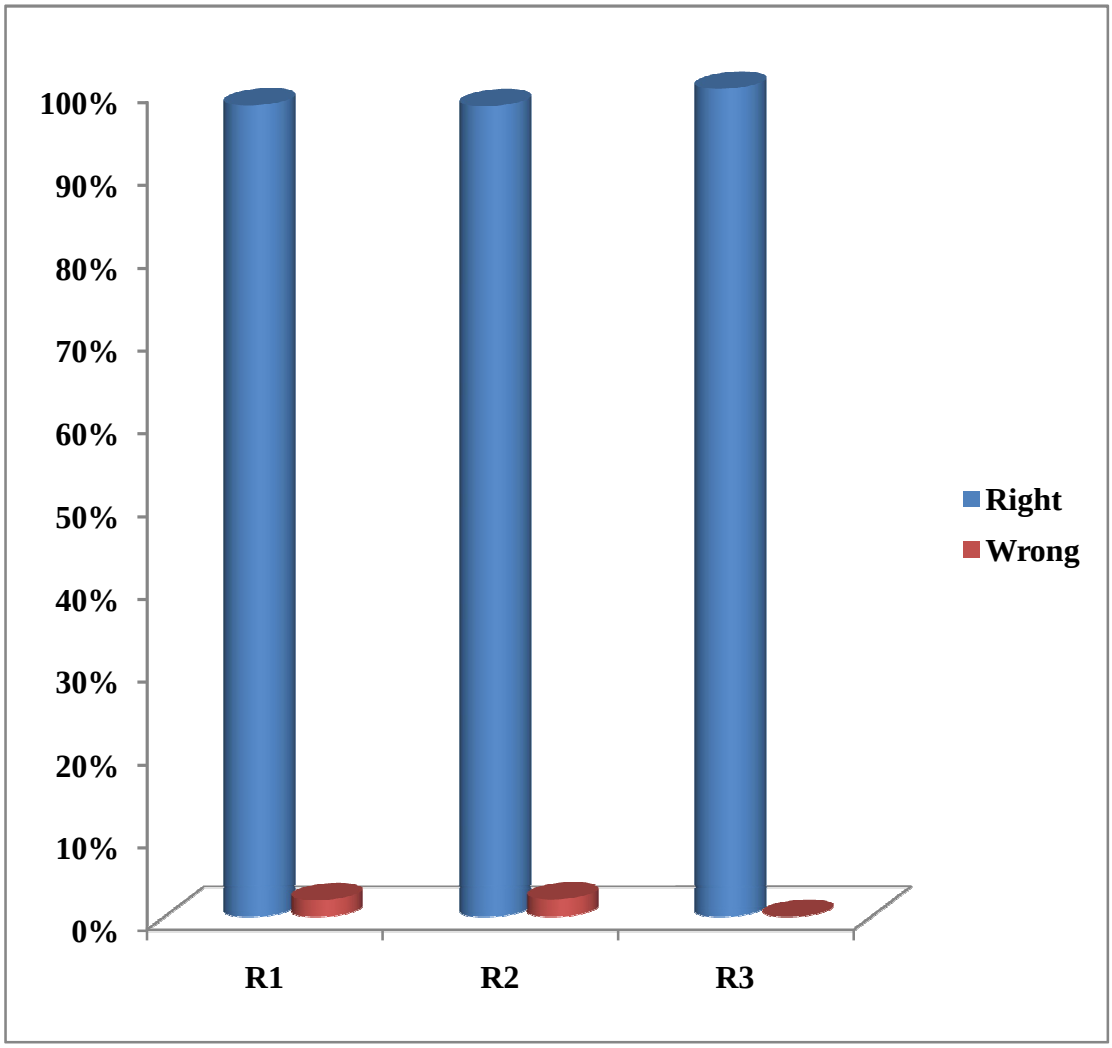
LOADING OF INSULIN –PRE AND POST COUSELLING

Loading of insulin	First visit	Second visit	Third visit
Right	98%	97.9%	100%
Wrong	2%	2.1%	0

This table shows loading of order of insulin is high in first visit itself, (98 %) and during subsequent visits it increased to 100% at 3rd review. Statistically it had no significant p value in all three visits.

CHART : 20

LOADING OF INSULIN



This chart shows that order of loading of insulin in each visit.

TABLE : 21

ACCURACY OF DOSE – PRE AND POST COUNSELLING

Accuracy of dose	First visit	Second visit	Third visit
Right	30%	56%	84.4%
Wrong	70%	40%	15.6%

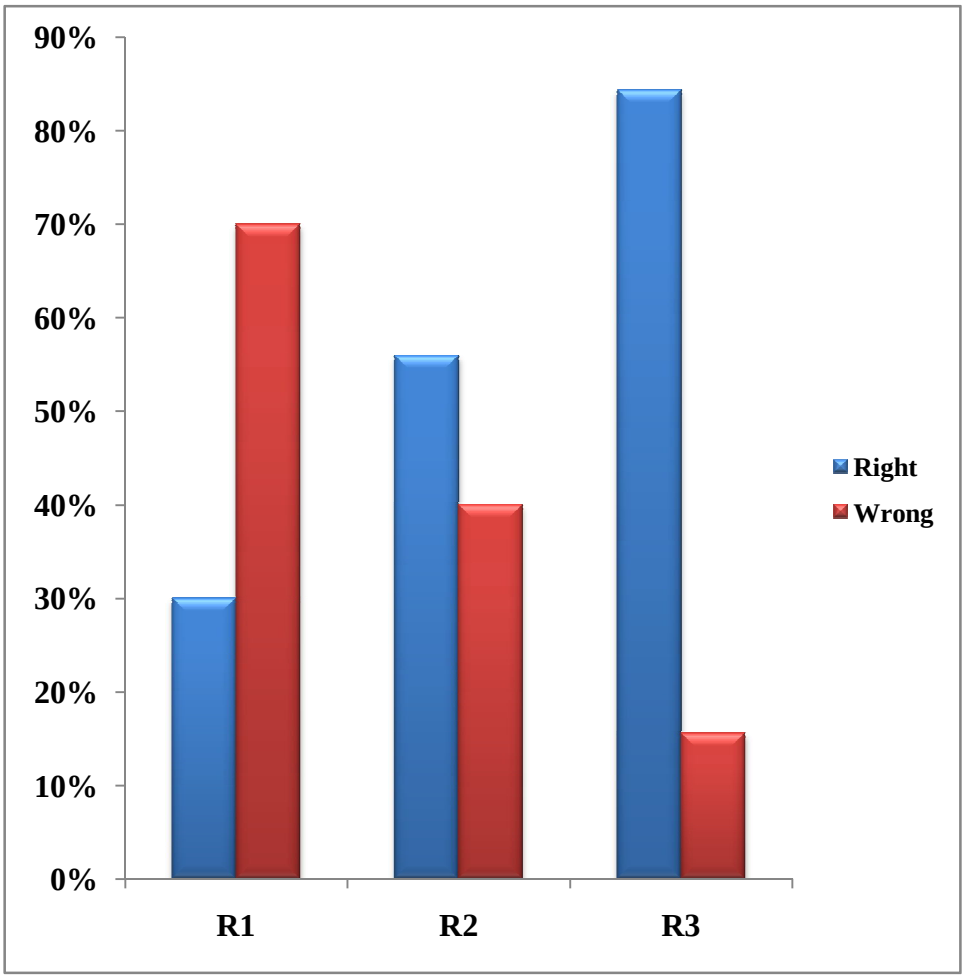
This table shows accuracy of dose of insulin in each visit. At first visit it was only 30%, but in second visit it reached 56 % (the increase in percentage is 26 %, with a significant p value of <0.001).

When comparing second and third visits, increase in percentage is 28.4 % and this was also statistically significant (p value <0.001).

While only 30% of patients were correct in accuracy of loading the insulin dose on first visit, 84.4% were correct in third visit, amounting to increase of 54.4 %.

CHART : 21

ACCURACY OF DOSE



This table shows the change in accuracy of dose in subsequent visits following counseling.

TABLE : 22

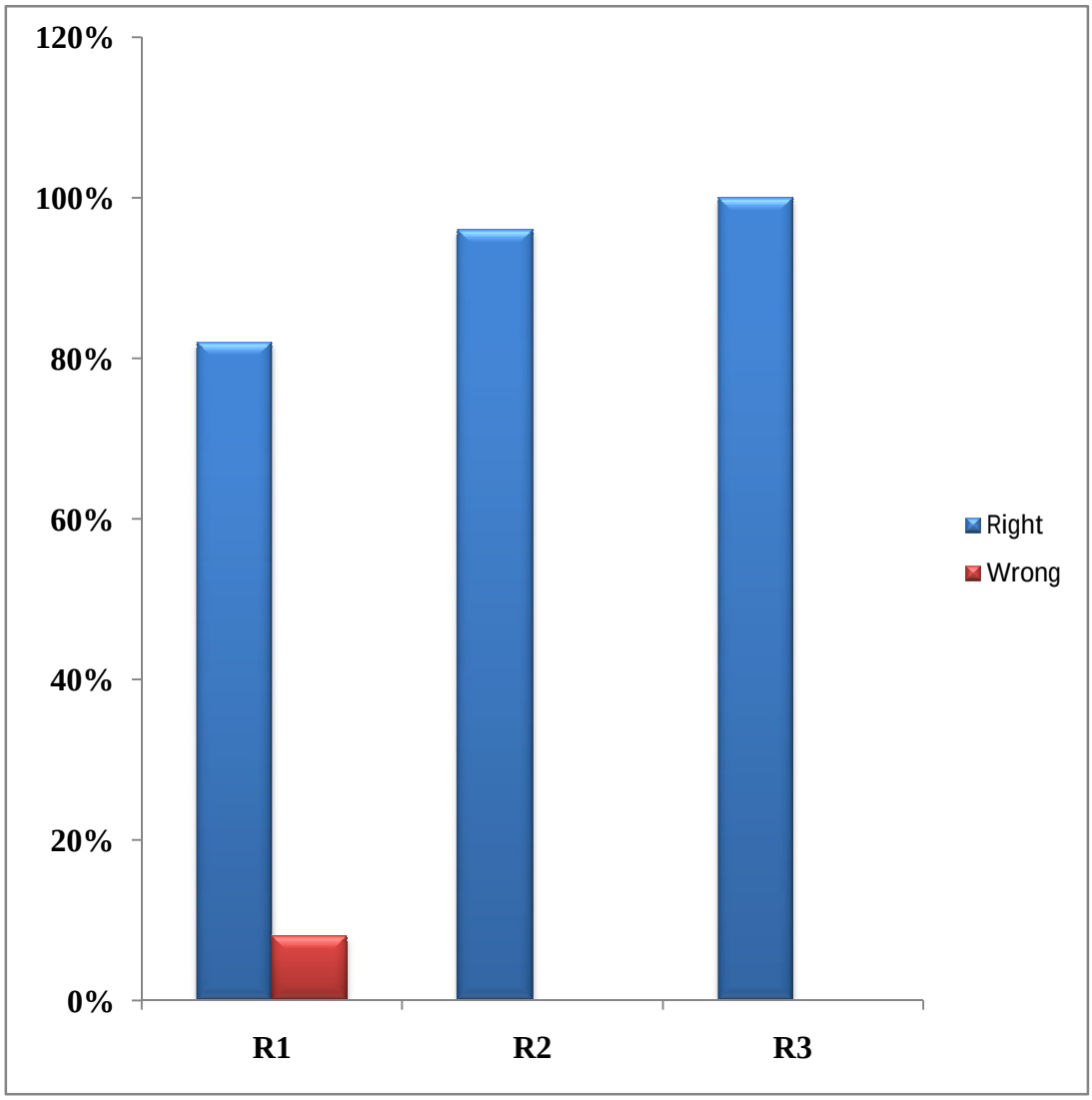
PRE INJECTION SKIN CLEANING – PRE AND POST COUNSELLING:

Skin cleaning	First visit	Second visit	Third visit
Right	92%	96%	100%
Wrong	8%	0	0

This table shows that 92 % of patients were correct in not cleaning the skin prior to injection on first visit and this increased to 96 % in second visit and further increased to 100% in third visit. But statistically this does not having a significant p value because increase in percentage is small.

CHART : 22

PRE INJECTION SKIN CLEANING



This table shows that pre skin cleaning percentage is high at basal level itself. So increase in percentage during subsequent reviews does not have significant p value.

TABLE : 23

SKIN PINCH APPROPRIATE – PRE AND POST COUNSELLING

Skin pinch	First visit	Second visit	Third visit
Right	52%	79.2%	93.3%
Wrong	48%	20.08%	6.7%

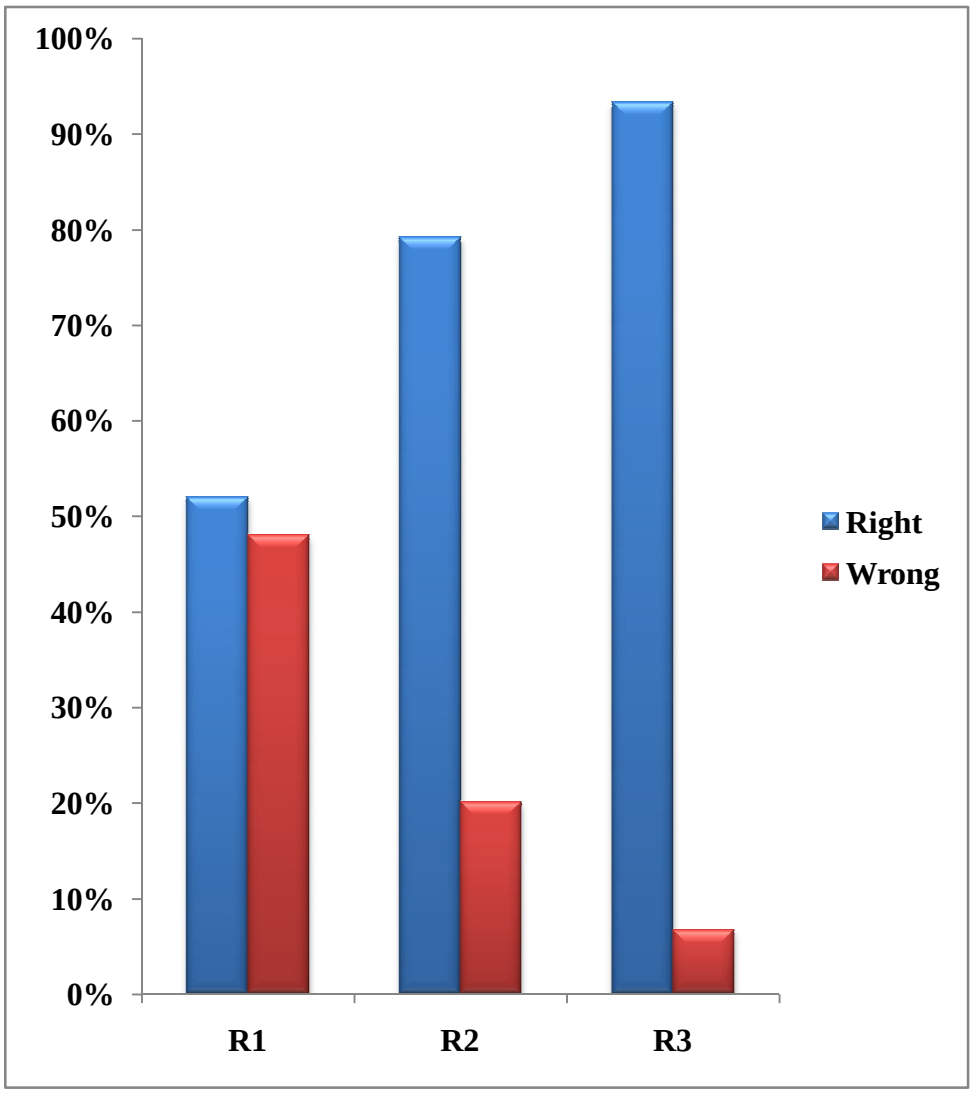
This table shows that appropriately done skin pinch was observed in 52% patients during 1st visit, on second visit it is further increased to 79.2% and this has a significant p value of 0.003.

During 3rd visit it further increased to 93.3% because of counseling. The increase in percentage is 14 % and it also has significant p value 0.001.

From basal level of 52 % to 93.3% is reached because of repeated counseling. Increase in percentage from first to third visit is 41.3 % and it also has significant p value 0.001.

CHART : 23

SKIN PINCH APPROPRIATE



This diagram shows the change in skin pinch appropriation following counseling in each visit.

TABLE : 24

NEEDLE ANGLE – PRE AND POST COUNSELLING

Needle angle	First visit	Second visit	Third visit
Right	42%	64.6%	71.1%
Wrong	58%	35.4%	28.9%

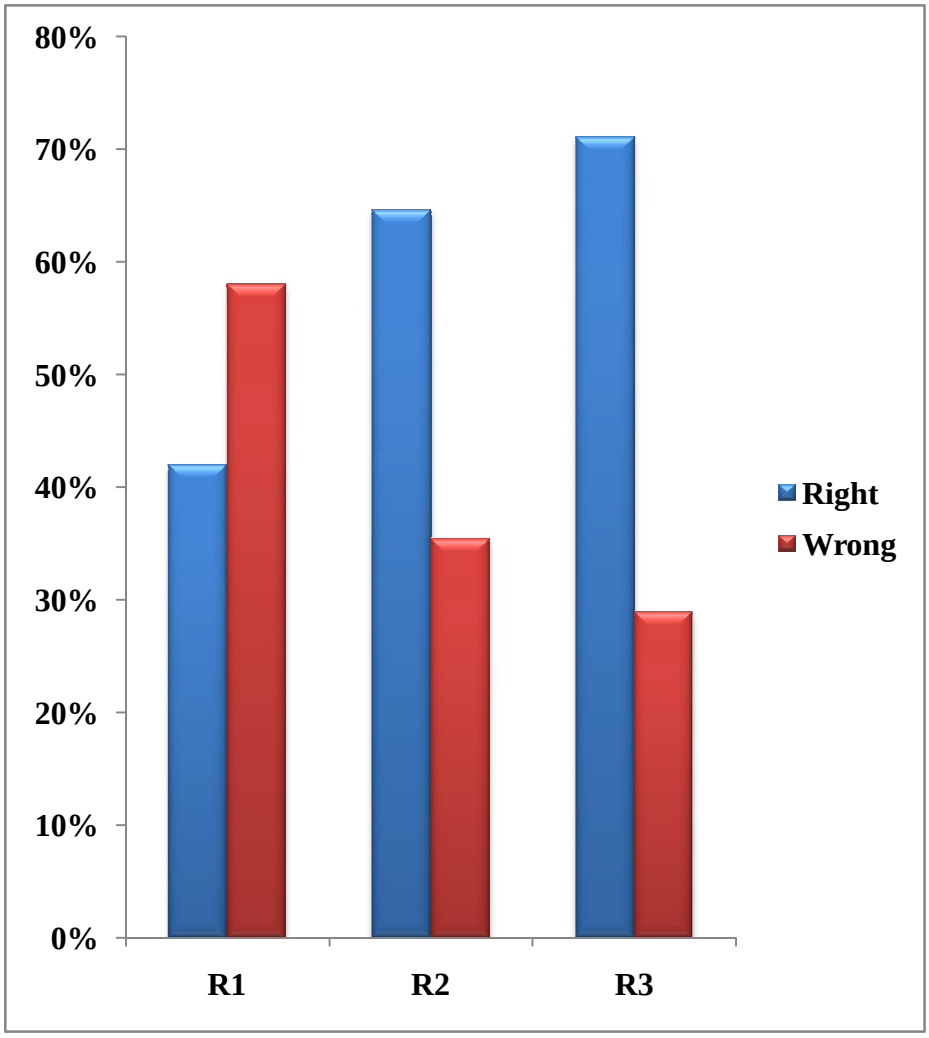
This table shows needle angling properly followed by 42% of patients in first visit which increased to 64.6% during second visit with a increase in percentage of 22.6%. This is due to the effect of counseling and has a significant p value of 0.005.

When compared to second visit, third visit had a further increase in percentage of 6.4% and has significant p value <0.001.

When comparing 1st visit with 3rd visit a total increase of 29.1% is observed and it has significant p value (0.005).

CHART : 24

NEEDLE ANGLE



This chart shows the increase in percentage of correct needle angling from 1st visit to 3rd visit.

TABLE : 25

DISPOSAL OF SYRINGE – PRE AND POST COUSELLING

Syringe disposal	First visit	Second visit	Third visit
Right	2%	20.8%	62.2%
Wrong	98%	79.2%	37.8%

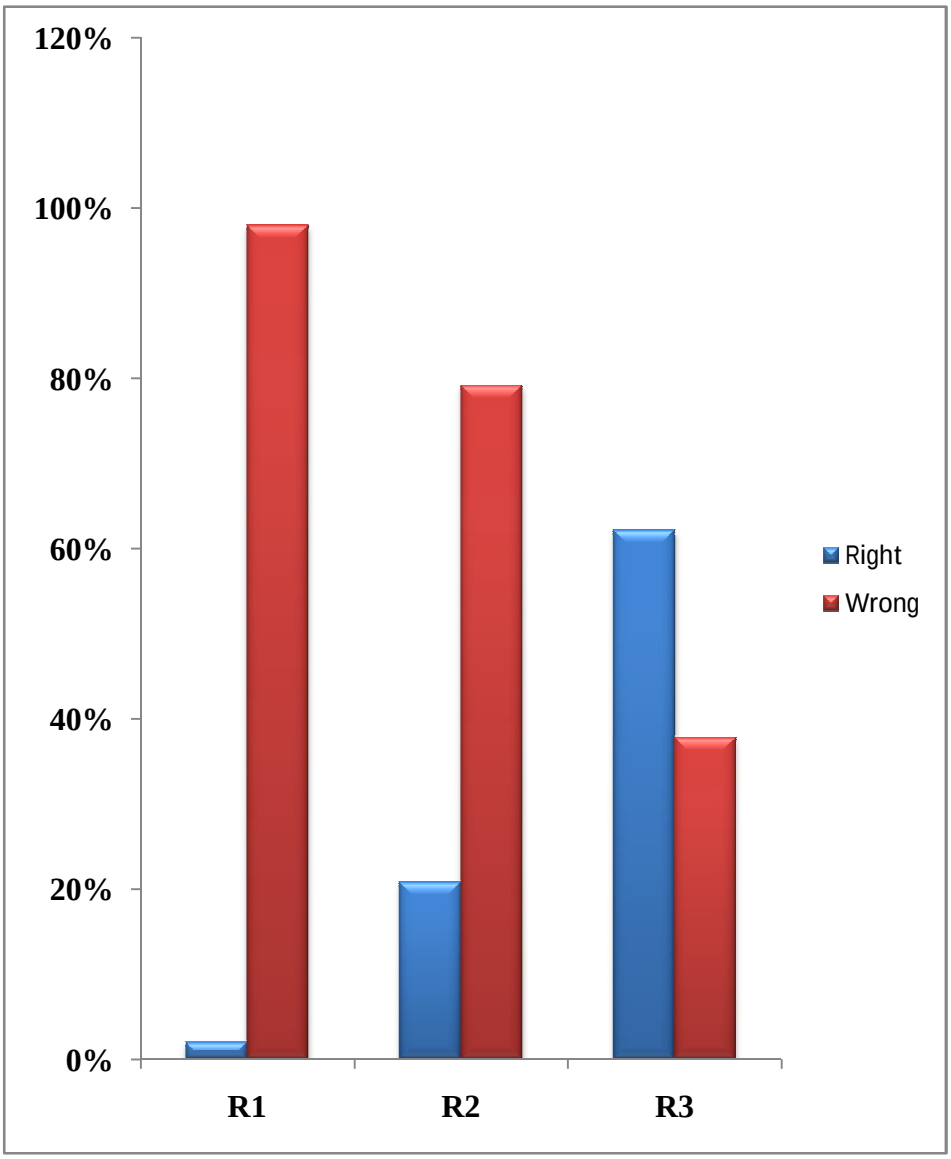
This table shows correct disposal of syringe was followed by only 2% of patients on first visit. It increased to 20.8% at second visit and 62.2% at 3rd visit (increase in percentage is 60.2%)

The increase in correct disposal of syringe had a significant p value (0.049) when it was compared between first and second visit.

Significant p value (0.040) was also observed when second visit was compared with the third.

CHART : 26

DISPOSAL OF SYRINGE



This chart shows practice of correct disposal of syringe is increasing gradually from 1st to 3rd visits.

TABLE : 27

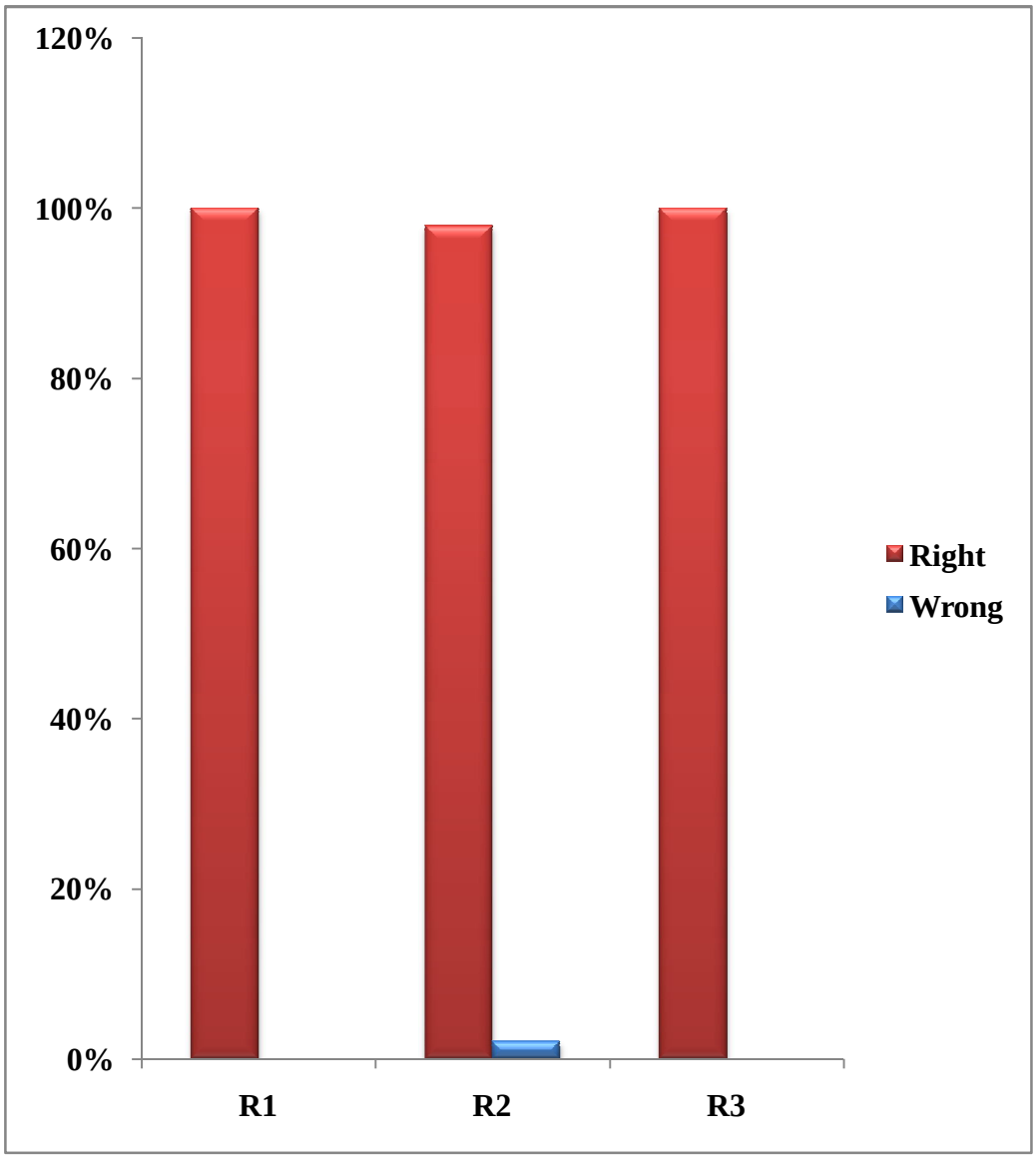
LIMB ROTATION – PRE AND POST COUNSELLING

Limb rotation	First Review	Second Review	Third Review
Right	100%	97.9%	100%
Wrong	0	2.1%	0

This table shows that correct practice of limb rotation was observed by all of the patients at 1st visit. But this parameter showed a slight decline (97.9%) at 2nd visit and again reached 100% at 3rd visit. This does not having any significant p value, when comparison was done between the visits.

CHART : 27

LIMB ROTATION



This chart shows limb rotation practice of patients on first and subsequent visits.

TABLE : 28

SITE ROTATION – PRE AND POST COUNSELLING:

Site rotation	First visit	Second visit	Third visit
Right	66%	91.7%	97.8%
Wrong	34%	8.3%	2.2%

The table shows the practice of site rotation in first visit and following counseling.

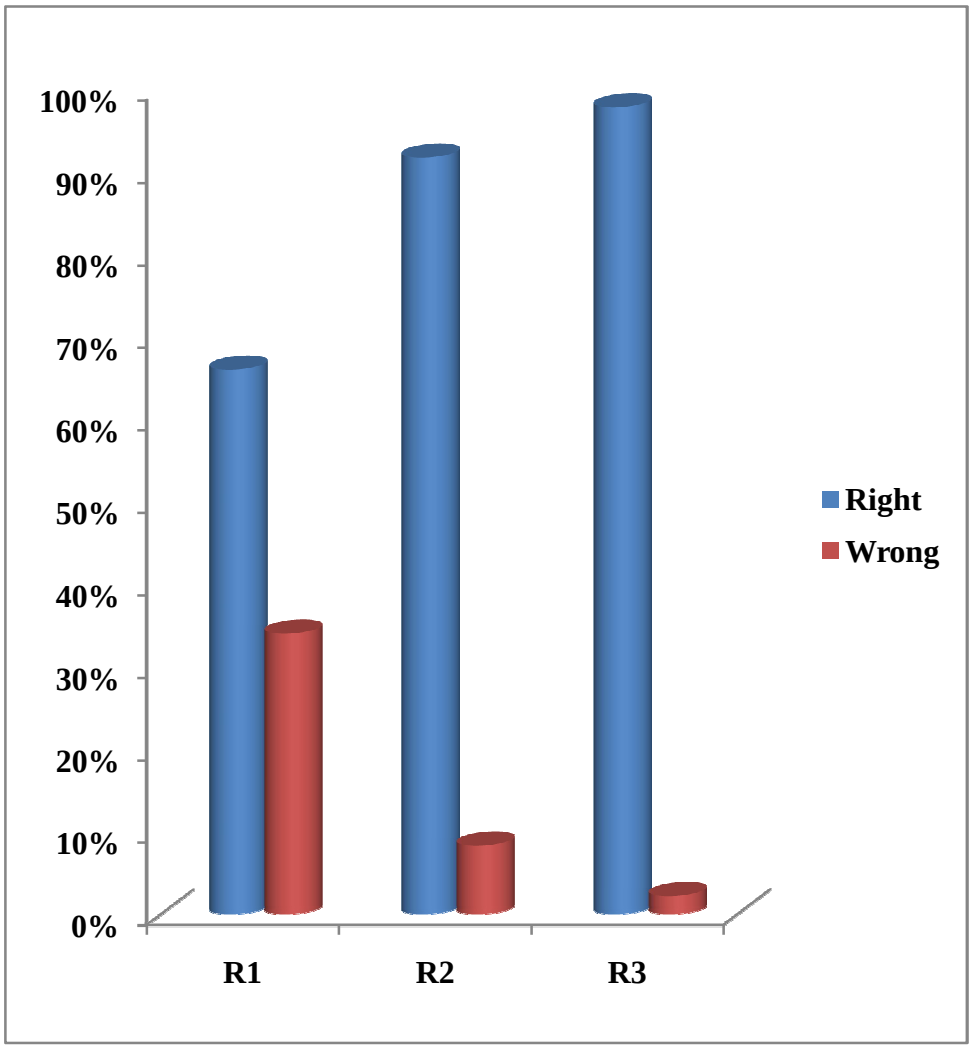
The increase in site rotation from first to second visit of 25.7% has a significant p value of 0.005

Increase of 6.7% from second to third visit has a significant p value of 0.0011.

After two counseling's only 2.2% were not performing site rotation correctly.

CHART : 28

SITE ROTATION



This chart shows site rotation on all visits and depicts the increase following counseling.

TABLE : 29

SITE RELATED PROBLEMS – PRE AND POST COUNSELLING:

Site problems	First visit	Second visit	Third visit
No	52%	64.6%	68.9%
Yes	48%	35.4%	31.1%

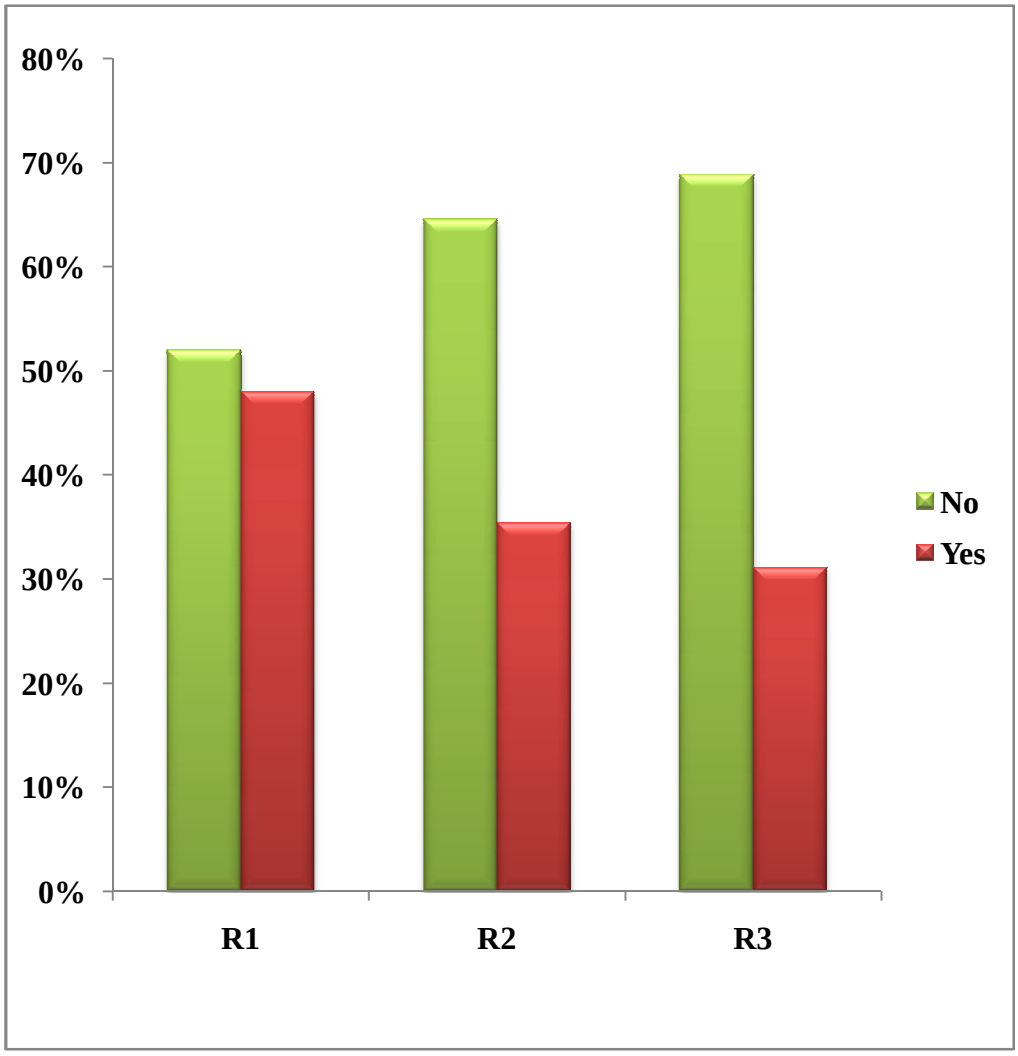
This table shows that site related problems decreased from 48% in first visit to 35.4% in the second visit, with a significant p value (<0.001).

This further decreased to 31.1% in third visit with a significant p value (<0.001).

Overall there was a 16.9% decrease in site related problems.

CHART : 29

SITE RELATED PROBLEMS



This chart shows the steady decline in site related problems on subsequent visits as a result of counseling.

TABLE : 30

HB A1C – PRE AND POST COUNSELLING

HbA1c Category	First visit	Second visit	Third visit
Good control	46%	62.5%	77.8%
Poor control	54%	37.5%	22.2%

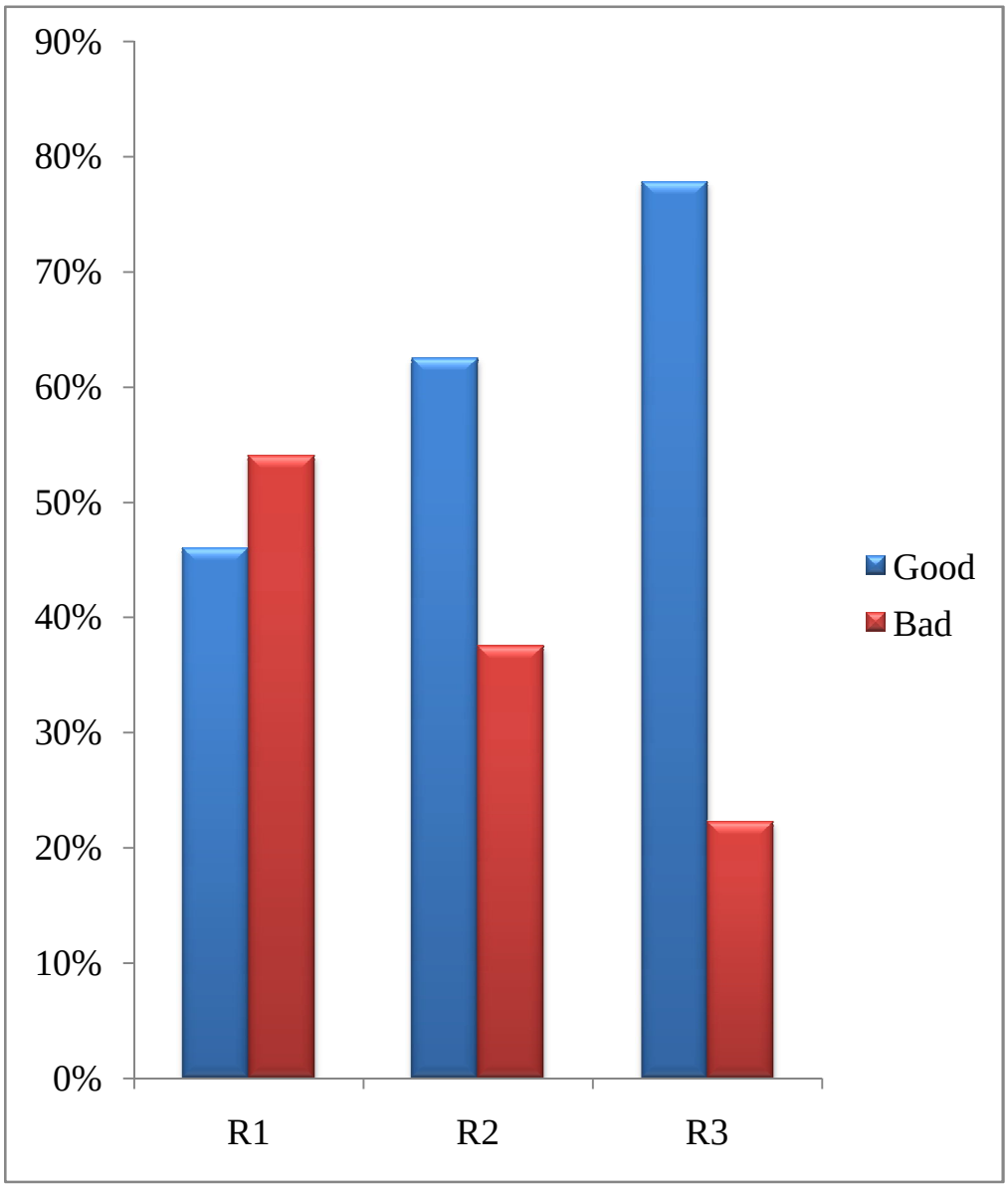
This table shows the level of metabolic control in first and subsequent visits. On first visit, only 46% had good control which increased to 62.5% in second visit and 77.8% in the third visit.

The increase of 16.5% following first counseling and 15.3% following the second counseling were statistically significant with a p value of <0.001in both.

Overall increase of patients with good control by 31.8% was also statistically significant with p value <0.001.

CHART : 30

HB A1C LEVEL



This chart shows percentage of patients with good and poor metabolic control on first and subsequent visits following counseling.

DISCUSSION

The incidence of type 1 diabetes is increasing worldwide especially in younger children. Unfortunately, there is little information on the incidence of type 1 diabetes and its management from India. Recent studies have emphasized the importance of strict glycemic control in the prevention and delay of chronic micro vascular complications of diabetes mellitus. These are few pediatricians and even fewer diabetes nurse educators trained in management of type 1 diabetes. This study to evaluate the problems in home based insulin therapy and effect of counseling in type 1 diabetic patients

AGE GROUP

The predominant age group in the study population was 5 to 9 years. 60 percentages of the patients belong to this age group in this study which is the most commonly involved age group.

GENDER

Female sex is involved more often than male sex in this study (64% as against 36%), but according to north American journal, both genders are equally affected and there is no gender preponderance .

DURATION OF ILLNESS

Highest percentages of patients were diagnosed with diabetes 12 to 18 months before. Newly diagnosed patients who were diagnosed less than 18 months were only included in the study as this is the period during which the patient as well as parent would be new to the concept of home treatment with injections and will need periodic reinforcement of the information provided at diagnosis. As time passes by they get adapted and trained to monitoring SMBG and appropriate injection techniques.

BODY MASS INDEX (BMI)

Most of the patients belong to normal BMI i.e. 90 % and none were in under nutrition category.

PARENTAL EDUCATION

Most parents had studied upto HSC followed by uneducated, while least number had done their graduation.

SELF MONITORING OF BLOOD GLUCOSE

On first visit self monitoring of blood glucose was done twice weekly by only 10% of patients which increased steadily following the two counseling sessions and was 46.7% at third visit.

Similarly patients doing SMBG occasionally declined steadily from 32% to none. These changes were statistically significant clearly showing the usefulness of the counseling given.

LOADING OF INSULIN

In this study 98% of patients were loading insulin in correct order on their first visit itself. This indicates that this aspect is well understood by the patients and may not warrant periodic reinforcement on subsequent visits.

ACCURACY OF THE DOSE

The accuracy of insulin dose was poorly understood and was hence inaccurate in most of the patients in this study which steadily increased with each counseling.

Even after two counseling and demonstration sessions, only 84.4 % of patients loaded insulin in correct dose and hence according to this study patients need some more counseling and demonstration on this parameter to reduce their errors.

PRE SKIN CLEANING

Most of the patients have correctly given the insulin without any pre skin cleaning at first visit itself and this point is clearly understood by them and do not need any further counseling & clarification on this parameter .

SKIN PINCH APPROPRIATE

Only half of the patients had performed skin pinch appropriately in their first visit, but following the counseling and demonstration sessions, more patients, but not all performed it correctly. This parameter too needs more clarification to reduce their errors.

NEEDLE ANGLE

Less than half of patients gave insulin injection in right angle on first visit, but this increased gradually with counseling and demonstration and reached 71.1% which is still suboptimal. Hence this aspect needs more demonstration to correct the errors. According to Sanjay Karla correct technique of injection not only reduces the local complications but is also helpful for metabolic control.

DISPOSAL OF SYRINGE

Only 2% of patients disposed the syringe in proper way on first visit, which increased to 62.2 % after two counseling sessions. Bio medical waste disposal is an important tool for prevention of serious infections and cannot be ignored.

LIMB ROTATION

This aspect is well understood and practiced by most of the patients. .

SITE ROTATION

This aspect also improved significantly with repeated counseling which is very important to prevent site related problems.

SITE RELATED PROBLEMS

The incidence of site related problems declined from half to one third of patients following two counseling and demonstration sessions. Site related problems like ecchymosis, lipohypertropy, atropy may cause not only disfigurement, but also painful injection and poor glycemic control leading to long term complications.

HIGHLIGHTS AND LIMITATIONS

This is a well planned and executed study covering many practical aspect of diabetes management, first of its kind in our population.

Limitations are small sample size and limited number of counseling sessions.

SUMMARY

According to this study the problems of home based insulin therapies are

1) SMBG – not done at optimal frequency in 90%.

2) Accuracy of loading - Correct in only 30%

3) Skin pinch appropriation – Correct in 52%

4) Needle angle – Correct in 42%

5) Disposal of syringe – Correct in only 2%

6) Site rotation – Correct in only 66%

7) Site related problems – Present in 48%

8) HBA1C - Good control in only 46%

Aspects which were found to be non problematic were

1. Order of loading insulin
2. Pre skin cleaning
3. Limb rotation.

Counseling and demonstration resulted in statistically significant improvement in all the deficient parameters. But the improvement was suboptimal; meaning none of the parameters reached 100%. This emphasizes the need for continued counseling and demonstration on all visits to the diabetic clinic.

CONCLUSION

The final conclusions derived from the study are

1. The problems of home based therapy are identified namely SMBG frequency, accuracy of dose, needle angle, skin pinch, local site related problem, site rotation and HBA1C control.

2. These problems improve significantly with counseling and demonstration. Hence the need for continued diabetes education is obvious.

3. Non problematic aspects of home based insulin therapy are order of loading insulin, prior skin cleaning, limb rotation and site rotation.

This study emphasizes the need for counseling by qualified personnel devoting plenty of time with both oral and video demonstrations to improve the quality and longevity of life of juvenile diabetics.

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DATA COLLECTION FORM - 1

A	B	C	D

1.	Serial no	
2.	Name Address	
3.	Age i)diabetic age	
4.	Sex (M/F)	
5.	Weight	
6.	Height	
7.	BMI (KG/M2)	
8.	Socio economic status	A B
9.	Parental education	X Y 1 2
10.	Family structure	

DATA ANALYSIS FORM – 2

A	B	C

1.	**Loading insulin** **pen or conventional syringe and needle** **if needle used** **(i). Appropriate syringe40u/ml used** **(ii). Order of loading of insulin in syringe** **Short first** **Intermediate next**	A B Remarks A B Remarks
2.	**Accuracy of dosage of insulin** **1 short acting** **2 intermediate acting** **3 dialing of pens**	A B Remarks
3.	**Inject by whom** **Mother father self or others**	A B C Remarks
4.	**Technique** **(i). Pre injection skin cleaning Yes or now** **If yes how** **(ii). Skin pinch appropriate or not** **(iii). Needle angle** **Inline with skin** **upto 45** **45to 90** **(iv). How many skin pricks per needle**	A B Remarks A B Remarks A B Remarks A B Remarks

5.	**Recap of needle** **Appropriate or inappropriate**	A B Remarks
6.	**Disposal of syringe/.needle** **Brought to clinic or not** **How preserved till disposal**	A B Remarks
7.	**(i). Injection site injection** **thigh arm abdomen others** **(ii). limb rotation** **(iii). site rotation**	A B C D Remarks A B Remarks A B Remarks
8.	**Maintain the timing in case of pens while withdrawal**	A B Remarks
9.	**(i). Local site complication** **(ii). site of injections** **(iii). site related problems** **A. hypertrophy** **B. atrophy** **C. scars** **D. Ecchymosis** **E. infections**	A B Remarks A B Remarks A B C D E Remarks
10.	**CBG Check up**	0 1 2
11.	**HBA1C**	

INFORMED CONSENT FORM

Study place: INSTITUTE OF CHILD HEALTH AND HOSPITAL FOR CHILDREN, DIABETOLOGY OPD & MEDICAL WARDS.

Title of the study: **"Evaluation of Home way insulin therapy and its compliance"**

Name of the investigator: **Dr.N.Soundararajan**

Name of the Participant: Age: Sex:

Hospital number:

1. I have read and understood this consent form and the information provided to me regarding the
2. I have had the consent document explained to me.
3. I have been explained about the nature of the study.
4. I have been explained about my rights and responsibilities by the investigator.
5. I will allow my child to undergo blood tests during the study whole heartedly.
6. I have informed the investigator of all the treatments my chikd is taking or have taken in the past including any native (alternative) treatment.
7. I have been advised about the risks associated with my child's participation in this study.*
8. I agree to cooperate with the investigator and I will inform him/her immediately if my child suffer unusual symptoms. *
9. I have not participated in any research study in the past.
10. I am aware of the fact that my child can opt out of the study at any time without having to give any reason and this will not affect my child's future treatment in this hospital. *
11. I am also aware that the investigator may terminate my child's participation in the study at any time, for any reason, without my consent. *
12. I hereby give permission to the investigators to release the information obtained from my child as result of participation in this study to the sponsors, regulatory

authorities, Govt. agencies, and IEC. I understand that they are publicly presented.

13. I have understand that my child's identity will be kept confidential if my data are publicly presented

14. I have had my questions answered to my satisfaction.

15. I have decided to be in the research study.

I am aware that if I have any question during this study, I should contact the investigator. By signing this consent form I attest that the information given in this document has been clearly explained to me and understood by me, I will be given a copy of this consent document.

Name and signature / thumb impression of the parents/guardian

Name _____ Signature_____

Date_____

Name and Signature of impartial witness:

Name _____ Signature_____

Date_____

Name and Signature of the investigator or his representative obtaining consent:

Name _____ Signature_____

Date_____

தகவல் படிவம்

ஆய்விடம் : அரசினர் குழந்தைகள் நல மருத்துவமனை, எழும்பூர்

ஆய்வாளர் : மரு.ந. சௌந்தரராஜன்

பங்குபெறுபவரின் பெயர் : வயது : பாலினம் :

மருத்துவமனை எண் : மாதிரியின் எண் :

ஆய்வு தலைப்பு:

நீரிழிவு நோய் உள்ள குழந்தைகளில் தனது வீட்டினிலே இன்சூலின் ஊசி போட்டுக் கொள்ளும் குழந்தைகள் / பாதுகாவலர் குறைபாடுகளை கண்டறிதல் தொடர்ந்து நேரடி ஆலோசனை மற்றும் வீடியோ ஆலோசனை மூலம் குறைபாடுகளை குறைக்க மேற்கொள்ளும் பரிசோதனை.

ஆய்வின் நோக்கம் :

1) நீரிழிவு நோய் உள்ள குழந்தைகளில் தனது வீட்டினிலே இன்சூலின் ஊசி போட்டுக் கொள்ளும் குழந்தைகள் / பாதுகாவலர் குறைபாடுகளை கண்டறிதல்.
2) தொடர்ந்து நேரடி ஆலோசனை மற்றும் வீடியோ ஆலோசனை மூலம் குறைகளை குறைத்து குழந்தையின் உடலில் சர்க்கரை அளவு தொடர்ந்து கட்டுப்பாட்டில் இருக்கிறதா என்பதற்கான சோதனை.

1) ஆய்வு

1) சர்க்கரை நோய் பற்றி முழுமையாக விவரித்து கூறிவிட்டு குழந்தைகள் / பாதுகாவலரின் அடிப்படை அறிவு மற்றும் 1. இன்சூலின் சரியான அளவு எடுத்துக்கொள்ளுதல் 2. முறையாக எடுத்துக்கொள்ளுதல் 3. இன்சூலின் ஊசி போடுவதற்கு முன்னும் 4.இன்சூலின் ஊசி குத்திக்கொள்ளும் சரியான முறை மற்றும் 5.இன்சூலின் ஊசி போட்ட பின்பு 6. ஊசியை சரியான முறையில் அகற்றுவது 7. ஊசி போடும் நேரத்தை சரியாக பின்பற்றுவது 8. உடம்பில் ஊசி போட்டுக்கொள்ளும் இடத்தை பரிசோதிப்பது மற்றும் பின் விளைவுகளை கண்டறிதல். 9. சர்க்கரையின் அளவு சரியாக உள்ளதா என்பதற்கான பரிசோதனை 10. நீண்ட நாள் சர்க்கரை அளவு சரியாக உள்ளதா என்பதற்கான பரிசோதனை இவை அனைத்தும் நேரடியாக உரையாடல் மூலம் சொல்லித் தருதல் மற்றும் வீடியோ மூலம் அவர்களின் குறைகளை கண்டறிந்து 0, 3, 6 ஆகிய மாதங்களில் சர்க்கரை நோயாளிகளையும் / பாதுகாவலர்களையும் வரச்செய்து இரத்தப் பரிசோதனை செய்து பார்த்து குழந்தையின் சர்க்கரையின் அளவு தொடர்ந்து கட்டுப்பாட்டில் இருக்கிறதா என்பதற்கான சோதனை

2) உங்கள் குழந்தையை பற்றி விவரங்களை யாருக்கும் தெரிவிக்காமல் பாதுகாக்கப்படும்.

3) இந்த ஆய்வில் பங்கு பெறுவது உங்கள் தனிப்பட்ட விருப்பமே. ஆய்வு ஆரம்பித்தபின் விருப்பம் இல்லை என்றால் அவைகள் விலகிக் கொள்ளலாம். அவ்வாறு விலகுவதானது தங்கள் குழந்தையின் சிகிச்சைக்கு எவ்வித பாதிப்பையும் உருவாக்காது.

4) ஆய்வின் முடிவகள் ஆய்வு நடக்கும் போதோ தேவை ஏற்படின் அல்லது ஆய்வு முடிந்த பின்னரோ தங்களுக்கு தெரிவிக்கப்படும். அந்த முடிவுகள் தங்கள் குழந்தையின் சிகிச்சைக்கு பேருதவியாக இருக்கக்கூடும்.

ஆய்வாளரின் கையொப்பம் **பெற்றோரின் கையொப்பம்**

மரு. ந. சௌந்தரராஜன்

நாள்

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No : 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr. N. Soundararajan,
Post Graduate in MD Paediatrics,
Institute of Child Health
Madras Medical College,
Chennai – 600003.

Dear Dr. N. Soundararajan,

The Institutional Ethics Committee has considered your request and approved extension of the study titled **"Evaluation of home based insulin therapy and its complications"** No. 07062014.

The following members of Ethics Committee were present in the meeting held on 03.06.2014 conducted at Madras Medical College, Chennai-3.

1.	Dr. C. Rajendran, M.D.	-- Chairperson
2.	Dr. R. Vimala, M.D., Dean, MMC, Ch-3.	-- Deputy Chair Person
3.	Prof. Kalaiselvi, MD., Vice-Principal, MMC, Ch-3	-- Member
4.	Prof. Nandhini, M.D. Inst. of Pharmacology, MMC, Ch-3.	-- Member
5.	Dr. G. Muralidharan, Director Incharge , Inst. of Surgery	-- Member
6.	Prof. Md Ali, MD., DM., Prof & HOD of MGE, MMC, Ch-3.	-- Member
7.	Prof. Ramadevi, Director i/c, Biochemistry, MMC,Ch-3.	-- Member
8.	Prof. Saraswathy, MD., Director, Pathology, MMC, Ch-3.	-- Member
9.	Prof. Tito, Director, i/c. Inst. of Internal Medicine, MMC	-- Member
10.	Thiru. Rameshkumar, Administrative Officer	-- Lay Person
11.	Thiru. S. Govindasamy, BABL, High Court, Chennai-1.	-- Lawyer
12.	Tmt. Arnold Saulina, MA MSW	-- Social Scientist

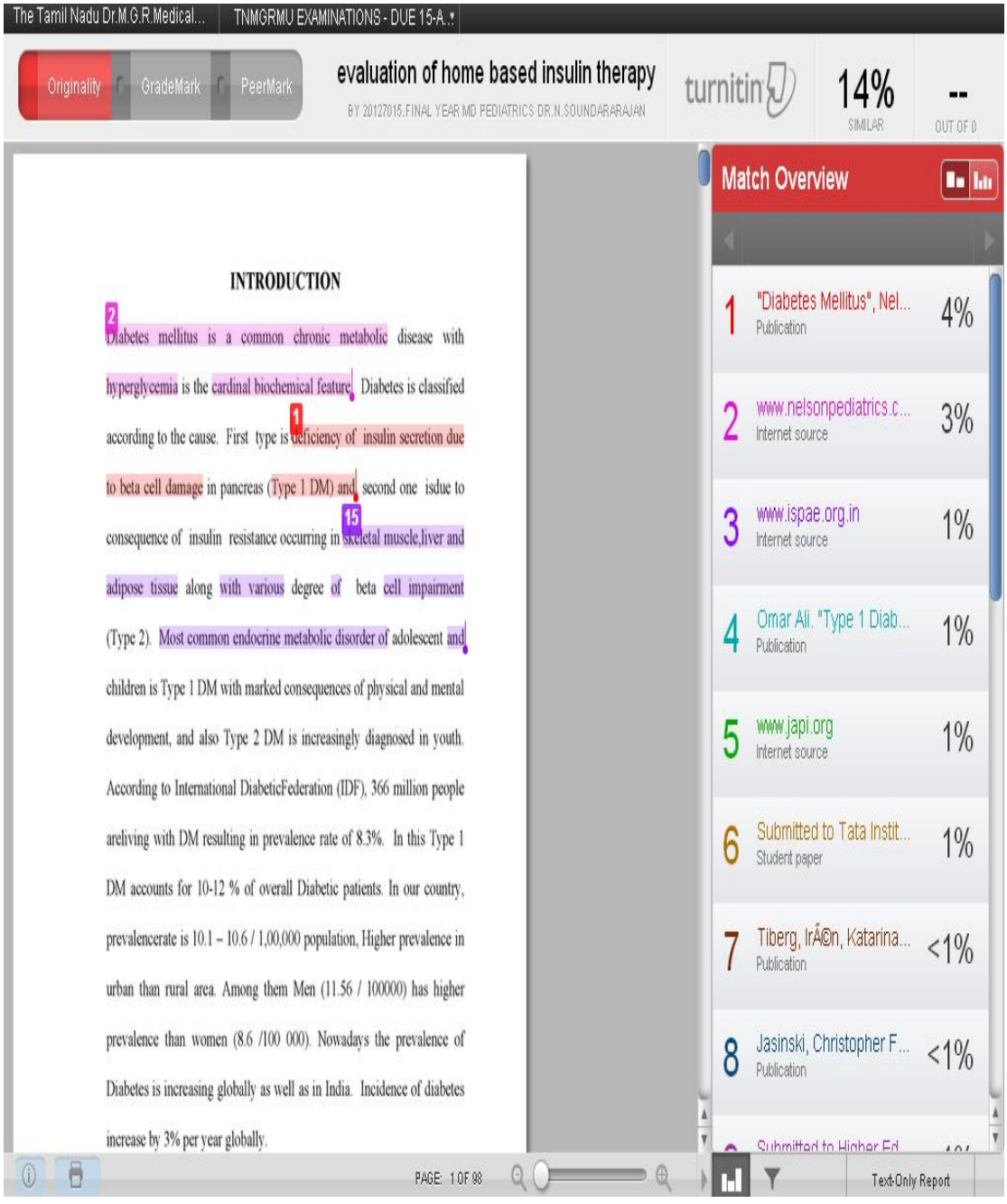
We approve the proposal to be conducted in its presented form.

Sd/Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, and SAE occurring in the course of the study, any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

Member Secretary, Ethics Committee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evaluation of home based insulin therapy
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INTRODUCTION
Diabetes mellitus is a common chronic metabolic disease with hyperglycemia is the cardinal biochemical feature. Diabetes is classified according to the cause. First type is deficiency of insulin secretion due to beta cell damage in pancreas (Type 1 DM) and second one isdue to consequence of insulin resistance occurring in skeletal muscle,liver and adipose tissue along with various degree of beta cell impairment (Type 2). Most common endocrine metabolic disorder of adolescent and children is Type 1 DM with marked consequences of physical and mental development, and also Type 2 DM is increasingly diagnosed in youth. According to International DiabeticFederation (IDF), 366 million people areliving with DM resulting in prevalence rate of 8.3%. In this Type 1 DM accounts for 10-12 % of overall Diabetic patients. In our country, prevalencerate is 10.1 – 10.6 / 1,00,000 population, Higher prevalence in urban than rural area. Among them Men (11.56 / 100000) has higher prevalence than women (8.6 /100 000). Nowadays the prevalence of Diabetes is increasing globally as well as in India. Incidence of diabetes increase by 3% per year globally.
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INTRODUCTION

MASTER CHART

S.NO	NAME	Age in years	Sex	BMI	Parental Education	Diabetic age in months	SMBG - R1	SMBG - R2	SMBG - R3	Loading of Insulin - R1	Loading of Insulin - R2	Loading of Insulin - R3	Accuracy of Dose - R1	Accuracy of Dose - R2	Accuracy of Dose - R3	Injection - R1	Injection - R2	Injection - R3	Pre Injection Skin Clean - R1
1	Anusya	3	2	2	2	3	2	2	2	1	1	1	2	2	1	2	2	2	1
2	Lakhsmi	3	2	4	1	3	3	3	2	1	1	1	2	2	1	1	1	1	1
3	Santhana lakhsmi	2	2	4	1	3	2	2	2	1	1	1	2	1	1	2	2	2	1
4	Simbu	3	1	3	2	3	3	2	2	1	1	1	2	2	2	1	1	1	1
5	Aishwarya	3	2	4	2	3	2	2	2	1	1	1	2	2	1	2	2	2	2
6	Dhava nithi	3	2	3	3	3	1	1	1	1	1	1	2	1	1	2	2	2	2
7	Manish kumar	1	1	4	2	2	3	2	1	1	1	1	2	2	2	2	2	2	1
8	Deena	2	1	4	2	3	1	1	2	1	1	1	1	1	1	2	2	2	1
9	Hemala	1	2	4	2	2	2	2	1	1	1	1	1	1	1	2	2	2	1
10	Vijay	3	1	4	2	3	2	2	2	1	1	1	2	2	1	1	1	1	1
11	lavanya	3	2	4	3	3	3	2	3	1	1	1	2	1	1	2	2	2	1
12	Srisha	2	2	4	1	3	3	2	2	1	1	1	2	1	1	2	2	2	1
13	princy	2	2	4	2	3	3	2	2	1	1	1	2	1	1	2	2	1	1
14	Abinaya	1	2	4	3	2	2	1	1	1	1	1	2	1	1	2	2	2	1
15	Nanilla kumar	2	1	4	2	2	3	2	2	1	1	1	2	2	1	2	2	2	1
16	Thilakavathy	3	2	4	1	3	2	2	2	1	1	1	2	2	1	1	1	1	1
17	Syed sreeja	2	2	4	3	3	2	2	1	1	1	1	1	1	1	2	2	2	2
18	Chandra	2	2	4	1	3	2	3	2	1	1	1	2	1	1	2	2	2	1
19	Sivagami	3	2	4	1	2	3	3	2	1	1	1	2	2	2	1	1	1	1
20	Abinaya sree	2	2	4	1	3	2	2	2	1	1	1	2	1	1	2	2	2	1
21	Surya	2	1	4	1	3	2	1	1	1	1	1	2	1	1	1	1	1	1
22	Bavatharani	3	2	4	1	3	2	2	2	1	1	1	2	2	2	1	1	1	1
23	Aswitha	2	2	4	2	3	1	1	1	1	1	1	2	2	1	2	2	2	1
24	Venkatesh	2	1	4	1	3	2	1	1	1	1	1	1	1	1	2	2	2	1
25	Sugumar	2	1	4	2	3	2	1	1	1	1	1	1	1	1	1	1	1	1
26	Sree kokilavani	2	2	4	1	3	2	1	2	1	1	1	2	2	1	2	2	2	1
27	Tamilarasan	3	1	4	1	2	3	2	2	1	1	1	2	2	2	2	2	2	1
28	Kalaiarasan	2	1	4	2	3	1	1	1	1	1	1	1	1	1	2	2	2	1
29	Jamuna	2	2	4	2	3	1	1	2	1	1	1	1	1	1	2	2	2	1
29	Poornima	2	2	1	2	3	2	1	1	1	1	1	2	1	1	2	2	2	1
30	Rajkiran	2	1	4	2	3	2	1	1	1	1	1	1	1	1	2	2	2	1
31	Kavya	2	2	4	1	3	2	2	2	1	1	1	2	2	2	2	2	2	1
32	Bavatharani	2	2	4	2	3	2	2	1	1	1	1	1	1	1	1	1	1	1
33	Sushtha	3	2	4	1	3	3	3	2	1	1	1	2	2	2	1	1	1	1
34	Swetha .	2	2	4	1	3	2	2	2	1	1	1	2	1	1	2	2	2	1
35	Sujith kumar	2	1	4	3	3	2	1	1	1	1	1	1	1	1	1	1	1	1
36	Karthik	2	1	4	1	2	2	1	1	1	1	1	2	1	1	2	2	2	1
37	Nivas paandi	1	1	4	2	1	2	1	1	1	1	1	2	1	1	2	2	2	1
38	sabitha	3	2	3	2	2	3	2	2	1	1	1	2	2	1	1	1	1	1
39	Thaman	1	1	4	2	2	2	2	1	1	1	1	2	1	1	2	2	2	1
40	veeramani	2	2	4	1	3	2	2	1	1	1	1	1	1	1	2	2	2	1
41	Kaviarasu	2	1	4	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1
42	Madhumitha	3	2	4	1	3	2	2	2	1	1	1	2	2	1	2	2	2	1
43	Swathi	2	2	4	2	3	3	2	1	1	1	1	1	1	1	1	1	1	2
44	Archana	2	2	4	2	3	3	2	.	1	1	.	2	2	.	2	2	.	1
45	Aruna	2	2	4	2	2	3	.	.	1	.	.	2	.	.	2	.	.	1
46	Pooja	2	2	4	2	2	3	2	.	1	1	.	1	1	.	2	2	.	1
47	Vijaya kumar	3	1	4	2	2	3	.	.	1	.	.	1	.	.	1	.	.	1
49	priya	2	2	4	2	2	2	1	1	2	2	1	2	2	1	1	1	1	1
50	Sailaja	2	1	4	2	2	3	2	.	1	1	.	2	2	.	2	2	.	1

MASTER CHART

Pre Injection Skin Clean - R2	Pre Injection Skin Clean - R3	Skin Pinch Appropriate - R1	Skin Pinch Appropriate - R2	Skin Pinch Appropriate - R3	Needle Angel - R1	Needle Angel - R2	Needle Angel - R3	Disposal of Syringe - R1	Disposal of Syringe - R2	Disposal of Syringe - R3	Limb Rotation - R1	Limb Rotation - R2	Limb Rotation - R3	Site Rotation - R1	Site Rotation - R2	Site Rotation - R3	Site Related Problem - R1	Site Related Problem - R2	Site Related Problem - R3	HBA1C - R1	HBA1C - R2	HBA1C - R3
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